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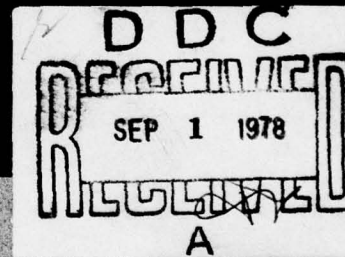
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# Bulletin of Prosthetics Research

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## THE IMPORTANCE OF AMPUTATION-LEVEL DETERMINATION

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*... guest editorial*

The objectives in selecting a level for lower-limb amputation include the removal of the gangrenous, infected, or traumatized portion of the limb while preserving the maximum length consistent with primary healing and successful prosthetic rehabilitation.

An assessment as to the adequate removal of the diseased tissue usually presents no problem in surgical judgment. In those cases in which amputation is done for trauma, the blood supply above the area of trauma is usually intact and healing of the amputation will not be compromised by vascular insufficiency. This picture is quite different in evaluating patients with occlusive vascular disease in whom the need for amputation is precipitated by rest pain, gangrene, or infection. In these instances, the likelihood of healing at the level immediately proximal to the diseased area is compromised by poor bloodflow. Since a greater blood supply is required to heal an incision than to simply maintain viability of intact skin, the presence of intact skin at a proposed level of amputation is no guarantee that the blood supply is adequate to heal an amputation at that level.

Until relatively recent times two alternative surgical approaches for amputation level selection existed. One approach was to carry out the most distal amputation that would circumvent the disease process, and then to simply carry out proximal revisions as would be necessary until an ultimate level was found at which healing

occurred. The second approach was to carry out a very high amputation, usually above the knee, on the thesis that this level could usually be depended upon to heal primarily, and thus the patient's hospital stay and morbidity would be minimized. Both of these methods of amputation selection are equally poor and are to be deplored. In the first instance, healing failure leading to subsequent proximal revision requires multiple anesthetics and surgical operations. These repeated exposures to surgical and anesthetic trauma must ultimately lead to increased morbidity, duration of hospitalization, and mortality. In addition, the final successful level may be considerably higher than what it would have been had the appropriate level been selected initially. In the second instance, routine above-knee amputation is associated with an unacceptably high mortality rate, and a poor success record for prosthetic rehabilitation in geriatric amputees.

In an attempt to establish amputation level criteria, various parameters of patient evaluation have been studied. These include the level of the most distal palpable pulse, skin temperature at the level of proposed amputation, and the angiographic patterns of collateral circulation. None of these parameters have provided the kind of quantitative criteria necessary to determine a sharp end-point for healing results and, hence, amputation level selection.

Approximately 10 years ago my team began to investigate the measurement of skin bloodflow at a proposed amputation level as a possible means of predicting success or failure of primary healing following lower-limb amputation. The radioactive isotope, Xenon<sup>133</sup>, was injected locally in the skin at a point along the course of the proposed amputation incision. The rate at which the isotope was removed was monitored by a counting device sensitive to radioactive emission, and was directly proportional to capillary bloodflow in the skin at that level. This method, first in a retrospective study, and subsequently a prospective study, has been shown to be a remarkably accurate means of level selection for primary healing. The technique was initially explored as a way to screen patients for proposed amputation at the below-knee level. Currently, we are using this technique to screen all amputation levels, including toe, Syme's amputation, transmetatarsal amputation, below-knee amputation, and knee-disarticulation amputation.

The net result has been not only that we are doing fewer above-knee amputations in favor of more below-knee amputations, but also that some patients who might otherwise have had a below-knee amputation are found to have a blood supply adequate to heal at an even more distal level such as transmetatarsal or Syme's amputation. Using this method for amputation level selection, amputation



#### Moore: Amputation Level Determination

at the above-knee level has become a relatively rare occurrence in our practice. For every above-knee amputation done and successfully healed in our program, there are 12 or more amputations done at some level that spares the knee joint.<sup>a</sup>

The improved healing rate seen in our program has been made possible not only by applying quantitative methods for amputation level selection, but also from improved surgical technique and post-operative care. The use of immediate postoperative prosthesis (IPOP) as modified and popularized by Burgess has had a monumental effect upon improving healing, reducing morbidity and mortality, and improving the extent and quality of prosthetic rehabilitation.

Since the ultimate goal of amputation is the rehabilitation of the patient on a permanent prosthesis, the likelihood of achieving this goal can be advanced in large part by using tests that will provide quantitative criteria for selecting the amputation level at the most distal portion of the limb that will heal, while at the same time encompassing the disease process. The use of this approach in an enlarging number of amputation centers will have far-reaching effects upon the quality of life, and the socio-economic independence, of a growing amputation population.

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<sup>a</sup> In the last 30 amputations in which Xenon<sup>133</sup> was used prospectively for level determination, there has been primary healing without revisions.



# **A PROPOSED TECHNIQUE FOR THE POSTOPERATIVE MONITORING OF SKIN TENSION IN BELOW-KNEE AMPUTEES<sup>a</sup>**

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## **INTRODUCTION**

The presence of abnormal amounts of fluid within body tissues (defined as edema) is generally considered detrimental to normal cell physiology, including wound healing following surgery. Appropriate postoperative wound management seeks to prevent, control and reduce edema.

The accurate monitoring of volume changes within a given mass of tissue can indicate the amount of edema present and thus reflect the effectiveness of the wound management utilized. Unfortunately, volume measurement is technically difficult in the clinical setting. The need to maintain wound sterility, wound support, and control of pain, and the limited efficiency and precision of present monitoring devices, all create technical obstacles. Displacement

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<sup>a</sup> This work was performed under Veterans Administration Contract No. V663P-784

studies using gases or liquids are cumbersome and can violate the sterile wound environment. A comparative study of tissue weight is also impractical, as are photographic, densometric, ultrasonic and radiographic (computerized axial tomography) systems.

This paper proposes a relatively simple technique for measurement of skin tension substantially at right angles to the suture line in a recent below-knee amputation limb. With this technique it is possible to monitor, at least by inference, the changes in pressure within the limb (and the presumed increase or reduction of edema) with various forms of treatment.

While an exacting qualitative readout is impractical at this time, it seems worthwhile to strive for a continuous readout indicative of edema. In our approach we have made numerous assumptions and generalizations about skin, tissue responses, edema formation, and both internal and external forces applied to the residual limb. Even with these obvious potential errors, it is felt that the readout we obtain will reflect, with adequate accuracy, changes in the degree of edema of the residual limb during treatment.

#### BACKGROUND

For a number of years, Prosthetics Research Study has been observing wound-healing following amputation. Methods designed to create an external physical environment more conducive to wound healing have been developed. The immediate postsurgical rigid dressing has been used successfully in many cases, with the technique as originally developed and with individual modifications (1). For the last 3 years, PRS has treated selected below-knee amputations with a Controlled Environment Treatment technique using gas as a dressing medium with the residual limb enclosed in a clear polyvinyl chloride bag (2). The parameters controlled within the environment are the external pressure, temperature, gas composition, and biological content (air cleaned to 99.998 percent sterility).

It is theorized that by maintaining the air pressure surrounding the residual limb at a level higher than that of the surrounding atmospheric pressure, edema can be more effectively controlled. By cycling the treatment pressure between high and low stages, vascular refilling is allowed.

It is difficult to determine, by visual observation of the residual limb, the effectiveness of this technique in controlling edema. It is, therefore, desirable to develop a technique to measure continuously any changes in edema that appear within the residual limb during Controlled Environment Treatment (Fig. 1).

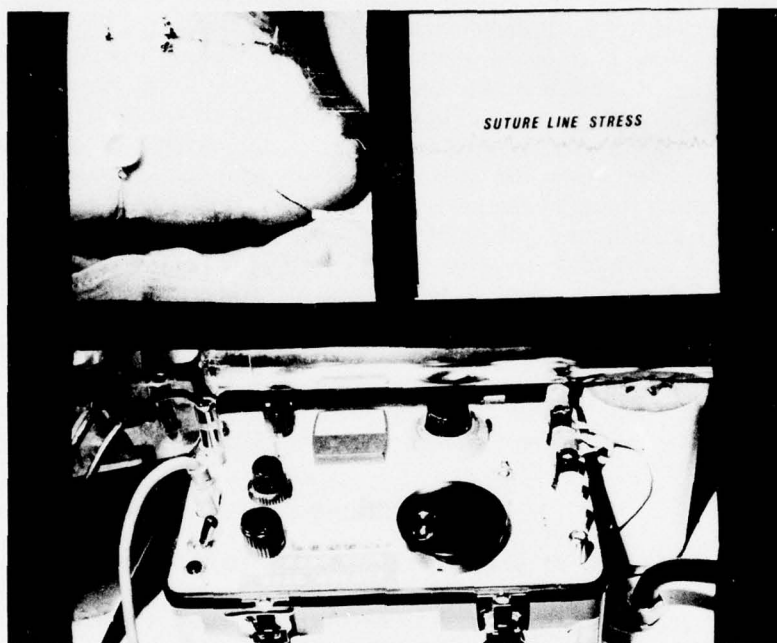


FIGURE 1. — Three elements of the instrumentation system. At top left, strain gages mounted on proving ring are seen sutured in place on residual limb. Transmission cables shown leading from transducer (strain gage) run to amplifier, shown below. Amplifier serves also as strain indicator with visual readout. Amplified signal is run to a strip chart recorder: top right photo shows typical strip chart produced.

#### BIOMECHANICAL MODEL

The biomechanical model developed to describe the amputated limb during the healing phase (the first 7 to 10 postoperative days) is that of a uniform cylinder with a hemispherical cap, the radius of the hemisphere being the same as that of the cylinder. Because the residual limb is horizontal, the hydrostatic head changes (pressure) are assumed to be uniform within the cylinder. If initially the incision runs horizontally across the hemispherical cap, and is assumed to be closed by  $n$  sutures spaced a distance  $s$  apart, a relationship in which the force acting on each suture is expressed as a function of the internal pressure can be developed. The tensile force  $f$  in the suture tends to compress the skin between the two inser-



tions of a given suture, but develops tension in the skin beyond. This portion of skin surrounding the incision is assumed to have a uniform but unknown stiffness  $K_1$ .

One side of the C-shaped proving ring of the transducer is tied into the suture, relieving tension in the suture near its insertion: the other side is anchored to a position conveniently removed from the incision. The transducer and its ties now bridge a small portion of skin on the hemispherical end of the limb. If the transducer/suture material is assumed to have a stiffness  $K_2$ , the force  $f$  is then borne by the parallel combinations of the two materials, skin and transducer. If the stiffness of the transducer ( $K_2$ ) is much, much greater than that of the skin ( $K_1$ ), as is probable, then the load may be assumed to be borne completely by the transducer. Therefore, the force normally acting on the suture alone across the incision is reflected in the tension sensed by the transducer.

#### EXPERIMENTAL DESIGN

The experimental instrument and method of application, developed to measure change in residual-limb edema, was based upon the following hypotheses:

1. The internal pressure of the essentially horizontal residual limb due to edema is uniform throughout the limb;
2. The measurement of changes in skin tension at any one point on the hemispherical cap accurately reflects changes in the internal fluid pressure (in the absence of hematoma);
3. The tangential strain (due to hoop tensile stress) of the skin is directly proportional to internal pressure;
4. The compliance of the strain-gage/suture material is infinitely rigid in comparison with the compliance of the underlying skin; and
5. Localized stress relaxation of the skin is not sufficient to compensate for changes of skin tension due to internal pressure.

The validity of these hypotheses is unproven at this point but each seems reasonable.

The instrumentation system developed consists of a strain gage, with its amplifier, recorder, and associated transmission cables mounted on the back of a Mk 1B CET machine (Fig. 2). The strain gage used was designed and developed specifically for this application: it consists of a split proving-ring with strain gages mounted to the ring to sense surface strain at the ring's point of maximum bending moment. The tensile force is applied at the attached eyelets

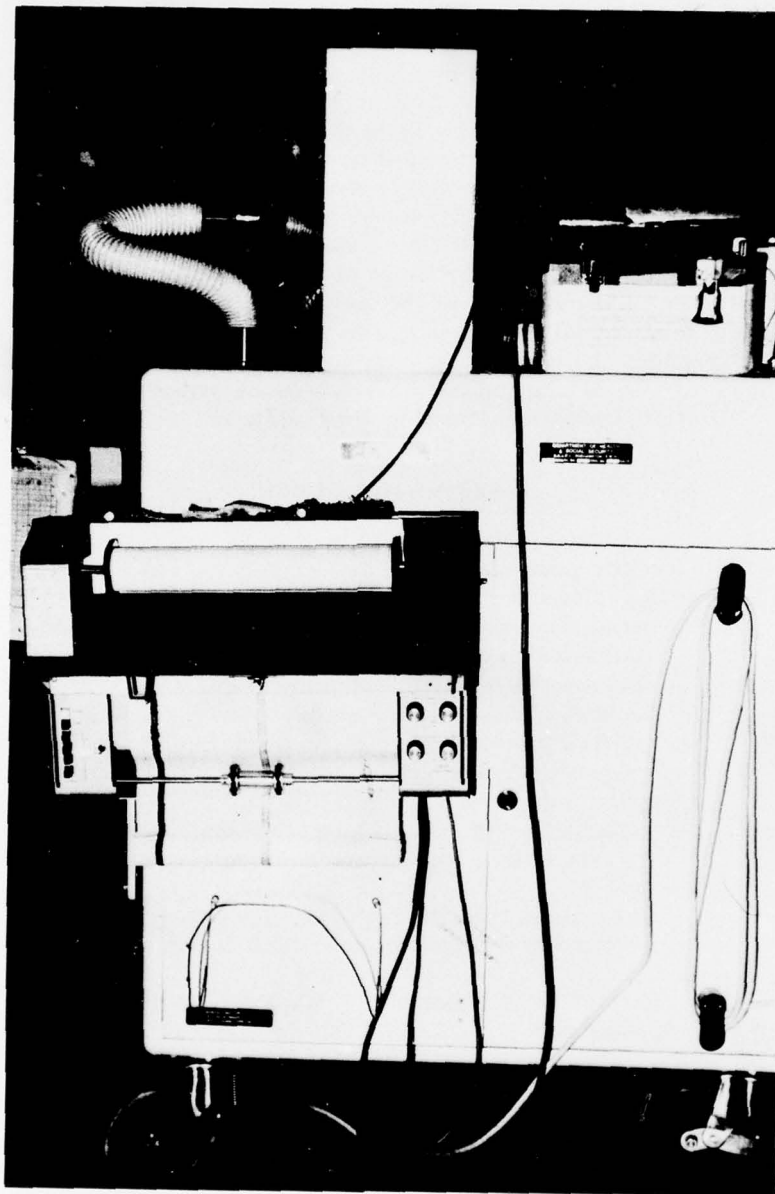


FIGURE 2. — The strip chart recorder is mounted on the rear of a CET machine. The amplifier is located on the top surface of the machine adjacent to the CET filter system.

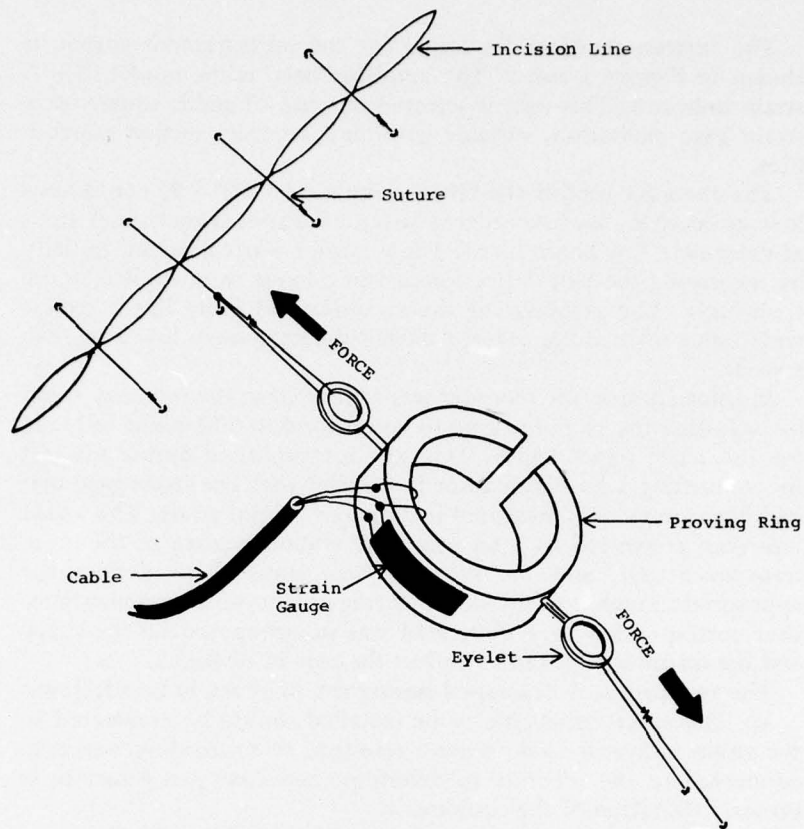


FIGURE 3. — Diagram illustrating components of the strain gage.

(Fig. 3) by the suture material. All strain gages and terminal strips are coated with an acrylic air-drying coating and are encapsulated with RTV silicone rubber.

Each strain gage unit (transducer, amplifier, and cable) is calibrated by applying static loads through the eyelets and recording the output strain signal on a strain indicator. The output signals for five known loads are recorded twice for each value, and the linear response of the transducer is determined by using a linear regression curve fit. The output of each strain gage is therefore specified in terms of the load  $Y$  in grams as the product of the regression coefficient and the output strain reading  $X$  ( $Y=AX$ ). The linearity of the fit is specified by the coefficient of determination  $r$  and is provided for each strain gage unit.



The instrumentation employed for the measurement system is shown in Figures 1 and 2. The amplifier used is the model P350A strain indicator. This unit is selected because of stable square-wave strain gage excitation, variable gain, and recorder output capabilities.

The recorder used is the Omniscrite Model 5213-5, continuous low speed strip chart recorder. This unit features two-channel input at extremely low chart speed. The recorder was calibrated initially by measuring the pen deflection as static loads were applied to the transducer. The response of the recorder was quite linear over a wide range of loadings (except during the extremely low level load tested).

In pilot studies, the recorder was calibrated in the recovery room by adjusting the amplifier gain to correspond to 500 grams full load for full chart paper width. This was accomplished during the test by connecting a known resistor in parallel with the strain gage that had been previously measured in terms of output strain. This strain was then converted to load using the response curve of the given transducer unit, and the recorder was adjusted to deflect the appropriate number of divisions. During prototype tests a resistance that corresponded to a 200g load was superimposed on the signal and the recorder adjusted to deflect the pen 40 divisions.

The test protocol developed during the pilot study is as follows:

1. The strain gage unit to be installed should be connected to the strain indicator to determine zero-load strain reading, and then connected to the recorder to determine zero-load pen position, in pretest calibration of the equipment.
2. The strain gage (the transducer without cables) was delivered to the operating prep team for sterilization at least 36 hours in advance of its intended use. Gas sterilization only was used.
3. Installation of the strain gage at the time of surgery was performed according to the strain gage protocol (see "Suturing-in Strain Gauge").
4. If Steri-Strips (3M Co.) are used, they should be applied before the final strain gage suture is tightened for preload. The strain gage should NOT be sutured over a Steri-Strip, as its stiffness is not known.
5. All cable connections are made in the recovery room. The initial preload readings, in terms of strain, are made from the strain indicator. The output of the strain indicator should then be connected to the strip chart recorder and initial preload measurement taken.
6. The tension measured by the strain gage should be recorded continuously on the strip chart recorder at 48 in.-per-day chart



speed, and intermittent strain readings with the strain indicator should be taken throughout the first 7 days of treatment. (The strain indicator readings require disconnection of the recorder cable at the strain indicator, to activate the strain indicator meter.)

#### SUTURING-IN THE STRAIN GAGE

We have found it convenient to locate the strain gage near the middle of the incision line. One end of the suture, after being tied off in the usual fashion, is looped through one eyelet of the strain gage (Fig. 4) and tied off. A loop length of approximately 2 cm is used to reduce the snubbing-post effect.

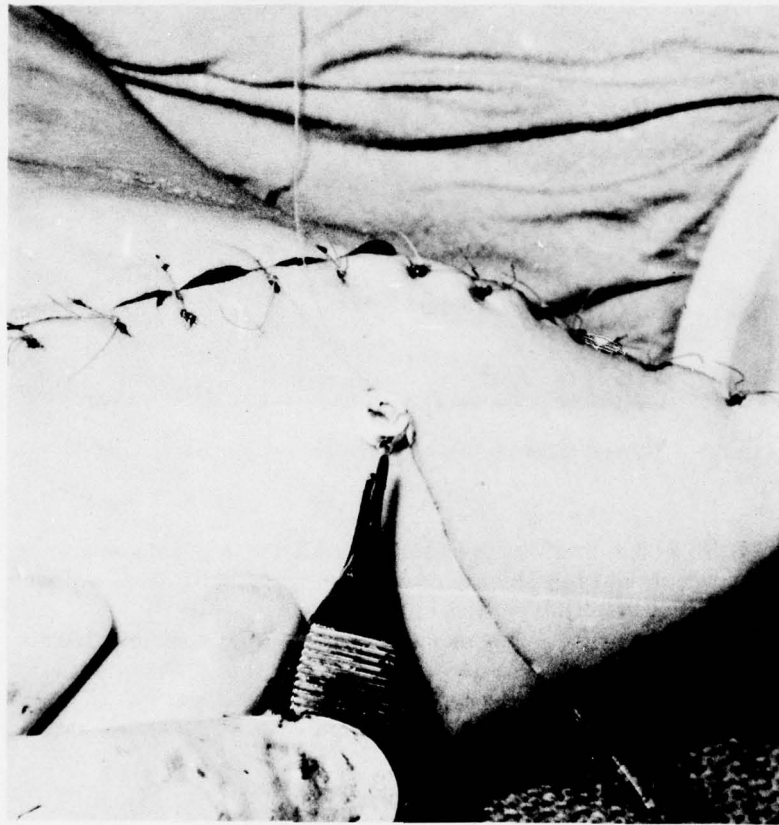


FIGURE 4. — The transducer is attached to a skin suture. Point of instrument indicates other eyelet of ring. Cables from strain gage run down and to the right out of picture.

A second suture is placed distally 4 to 5 cm from the first suture (Fig. 5). This suture is looped through the remaining strain gage eyelet but not tied off.

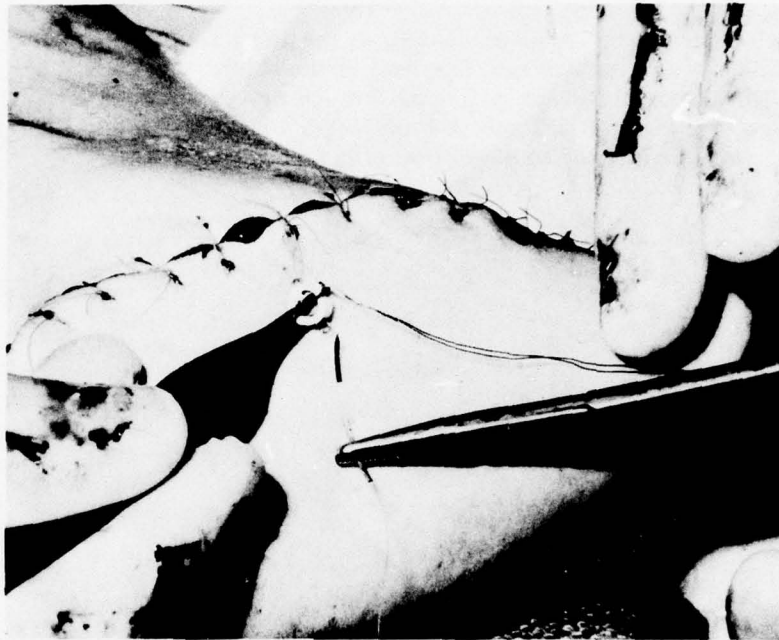


FIGURE 5. — The final transducer suture is attached at a position removed from the skin sutures.

At this point, Steri-Strips should be added if they are going to be used: care should be taken to ensure that no Steri-Strips pass under or over either tie-down sutures or the strain gage (Fig. 6).

After Steri-Strips are in place, the final suture can be tightened to place the strain gage under preload. (At this time, no specific amount of preload has been decided upon.) Figure 7 shows a sutured-in strain gage without Steri-Strips.

#### ANALYSIS

The continuous strip chart recordings of strain fluctuate with the CET operation and daily patient activity, as well as with long-term



FIGURE 6. — Steri-Strips have been placed over the incision and skin sutures, avoiding the transducer and its sutures. The second transducer suture is then tightened for correct preload.

edema changes. During pilot studies, the data were reduced to demonstrate mainly long-term edema control: the total strip chart record was reduced to a chart that fits data for the first 7 days of treatment on a graph measuring only 8 in.  $\times$  10 in. This compression of the data was accomplished by measuring the mean tension (halfway between maximum and minimum cyclic fluctuations) at each hour mark throughout the first 7 days. These loads were then plotted on a condensed scale to indicate long-term changes more readily.





FIGURE 7. — Strain gage in place, without application of Steri-Strips.

#### PRELIMINARY RESULTS

The skin tension strain gage has been used successfully on three patients (Fig. 8). (Five subsequent patients have experienced minor equipment problems which invalidated their data.) This pilot study indicates that there is a distinctive increase in residual limb pressure, peaking a few days postoperatively and not in hours as one might expect.

On the fifth postoperative day, patient No. 1 was found to have compromised the pressure integrity of his treatment by inserting his hand in the seal. This allowed more air to escape, thus lowering the pressure, especially during the high pressure portion of the pulse cycles. The effect can be seen in the sharp rise in tension/edema: when the air pressure was restored, tension/edema reduced sharply (Fig. 8). No special techniques were used to monitor the patients, so it is not known if some of the other irregularities could be

Burgess et al.: Postoperative Monitoring of Skin Tension

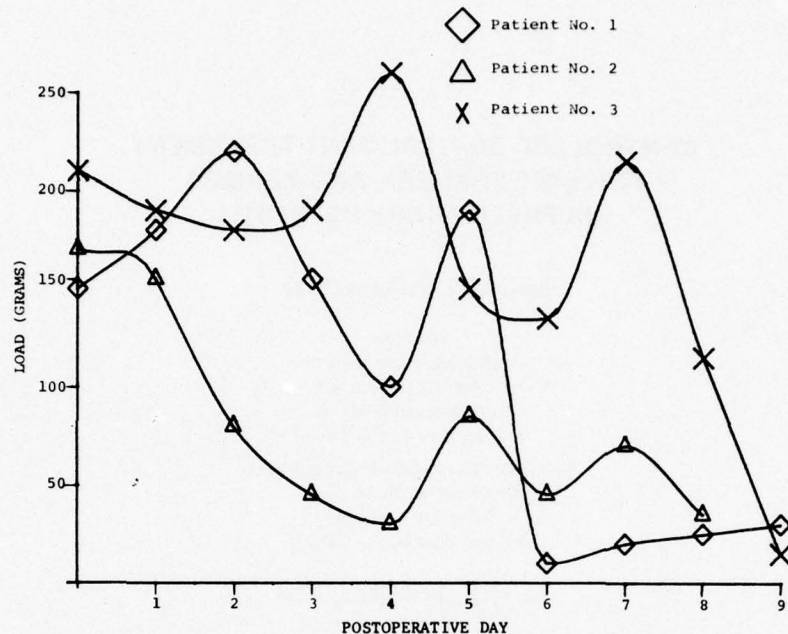


FIGURE 8. — Graph represents strain gage load in grams, three patients.

attributed to the same cause.

This paper describes the preliminary work accomplished in developing an instrumentation system to indicate changes in the edema in the residual limb of below-knee amputees in the early postsurgical phase. The instrumentation described in this report has been demonstrated to function well, and appears to meet all original design criteria. Its reliability and representativeness can only be determined by its use in a long term comprehensive study.

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**CONTROLLED ENVIRONMENT TREATMENT  
FOR LIMB SURGERY AND TRAUMA  
(A PRELIMINARY REPORT)<sup>a</sup>**

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**ABSTRACT**

This paper demonstrates a new approach to postsurgical and post-traumatic wound management in the lower limbs. Our own results of 20 below-knee amputations are documented. A less detailed report is then given of experience with an additional 20 amputees: this second group includes experience not only here at Seattle but at five other centers in the United States. The same method for wound management and for control of edema was employed in all cases.

The method, Controlled Environment Treatment (CET), uses filtered air as a dressing medium, with a control console to maintain the pressure, constant or varying, according to a preset program. Temperature and humidity are also controllable, as is gas composition. The limb, together with its controlled environment, is contained within a pliable, transparent, treatment bag, which permits

<sup>a</sup> This work was performed under Veterans Administration Contract No. V663P-784



inspection and palpation of the wound site without disturbing the bacteriologically sterile air within the chamber. A special seal reduces air leakage yet avoids constriction of the limb.

This CET system was originally developed by the Department of Health and Social Security, Biomechanical Research and Development Unit, Roehampton, England. Subsequent developments are also noted of an improved Mark II CET Unit and of simpler, related, management systems for conditions not requiring sterile environments.

## **BACKGROUND**

### **Background on Wound Healing**

Wound healing has been described as "the foundation of surgery." Every traumatic and incisional injury initiates an orderly sequence of cellular and molecular events which serve to restore structural continuity (11). New operations, new techniques, and new systems of surgical management must all rely on wound healing for success.

The voluminous literature on the subject of wound healing in the past has related to an understanding of the physiological response of injured tissue, as exhibited by the repair process (11,12, 21,24). Excluding burn care, little attention has been paid to the physical treatment of the postoperative wound. Conventional postoperative management consists of application of a variety of sterile dressings. The problems associated with these conventional dressings are the lack of adequate control over pressure, humidity, temperature, immobilization, and sterility of the wound site. Investigations have shown that pressure under "pressure support dressings" is variable, unpredictable, often poorly localized, and in limbs can frequently have a proximal tourniquet effect. Moisture, humidity, healing wound-surface environmental temperature, and sterility under conventional dressings, are difficult to monitor and control. The wound is invisible and can only be observed by periodic removal and renewal of dressings. This process removes any blood and serum which have oozed from the wound, but dressing changes may be painful for the patient. Removal of a potential culture medium must be balanced against the risk of new contamination. The pressure of the new dressing again is variable. Edema may increase while the wound is exposed.

Regarding pressure, until recently very little has been added to Blair's classic treatise, "The Influence of Mechanical Pressure on Wound Healing," published in 1924 (3). As we come to understand



more fully the pressure relationships within injured tissue, and the effects of externally applied pressure, one realizes how generally haphazard has been the use of pressure in post-surgical and post-traumatic wound management (1,15,16,17,23).

The argument is advanced that this area of treatment is not so important and that present techniques, though not precise, appear to be adequate. This attitude is not justified by current knowledge of the physiology of wound healing. Cellular repair and regeneration are among the most basic and fascinating aspects of living matter. An increasing understanding of these life processes parallels the rapid accumulation of knowledge in genetics. The clinician is committed to as much practical application of this knowledge as is possible in support of the body and the healing process: a more complete understanding of the biomechanical, electrical, chemical, and genetic forces involved in the repair process accentuates the importance of presenting to the healing tissue the most favorable physical environment.

#### Background Leading to Development of Investigation

Our interest in the clinical investigation of the wound healing environment for the past 13 years has been directed toward amputations (4,5,6). The amputation provides an excellent clinical laboratory for wound healing study. All tissues of the limb are severed in cross section, each must heal in its specific manner under the broad canopy of general principles of tissue repair. The amputation is terminal, and this anatomical fact permits the application of an external environment which need not concern body structure distal to the site of surgery. Thus there is latitude for manipulation of the physical environment not present in segmental or intercalary surgery and trauma.

A majority of amputations are performed for ischemia. Post-surgical circumstances favorable to healing are especially critical when cell viability is less than optimum. Thus, amputations for ischemia present a special challenge in the area of wound healing. Since residual limb function and prosthetic rehabilitation are so closely related to amputation level, the surgeon must measure success against the dual yardsticks of distal amputation level and primary wound healing. This is a particularly critical choice in the case of a lower limb in a geriatric patient.

In 1964 we set out to clinically evaluate wound healing following amputation when using a rigid dressing with pressure interface (8). Early function was obtained, in both the upper and lower limbs, by use of detachable functional terminal units to allow restricted ambulation in lower limb amputations and terminal device

control in upper limb amputations. Our system was modified from reported techniques dating back to World War I: e.g., Wilson (27) (Fig. 1) and more recently by Weiss (26) and Berlemont et al. (2). It has come to be known as Immediate Postsurgical Prosthetic Fitting, or IPPF.



FIGURE 1. — Forerunner of modern IPPF techniques as outlined by Wilson, 1922. (Illustration, reprinted courtesy Journal of Bone & Joint Surgery, appeared in Vol. IV, No. 2, April 1922, page 240.)

The rigid dressing (IPPF) system, as we use it, is designed to provide an improved postsurgical physical environment for amputation wound healing. It incorporates wound support, immobilization, external pressure both constant and intermittent, non-occlusive dressings to control moisture and humidity, reasonable sterility, and active residual limb use consistent with the dressing. IPPF is now a relatively standard system of postsurgical management in many areas throughout the world (14,18,19,20,25).

The study reported here relates to a refinement and greater degree of control of the modalities just outlined. The method to be described, i.e., Controlled Environment Treatment (CET), uses equipment developed by the Biomechanical Research and Development Unit, Department of Health and Social Security, Roehampton, England. Clinical investigation of CET in the United States

began in March 1974, at the VA Hospital, Seattle, Washington, under the supervision of the Prosthetics Research Study, and this report records our specific experience in the treatment of 20 below-knee amputations between March 1974 and December 1975, using Mark I equipment.

Then, during the summer of 1975, additional CET units were provided to the San Francisco VA Hospital (Vascular-Surgical Service), San Francisco, California, the Castle Point VA Hospital (Surgical Service), Castle Point, New York; the Duke University Medical Center (Departments of Orthopaedic and Hand Surgery), Durham, North Carolina; the Rancho Los Amigos Hospital (Rehabilitation Engineering Center), Downey, California; and to the University of Washington School of Medicine (Departments of Orthopedics and Surgery), Seattle, Washington. Some of the preliminary results of these efforts will also be presented in this report, though separate publications are anticipated when more extensive series are completed.

At Seattle and elsewhere, the method also has been used in a variety of limb surgical procedures and trauma including burns, hand surgery, fractures, sprains and dislocations, crush syndromes, and for the relief of edema. Some results are presented in these areas.

#### **DESCRIPTION OF METHOD AND EQUIPMENT**

CET uses filtered air as a dressing medium. Equipment in a control console maintains air pressure, constant or varying, on the enclosed part of the limb. The gas composition, duration and magnitude of pressure phases, temperature, and humidity can all be controlled. The limb, together with its controlled gaseous environment, is contained within a polyvinyl chloride (PVC) treatment bag. Pliability and transparency of this dressing allow inspection and palpation of the wound site without disturbing the bacteriologically sterile gas within the chamber. A special seal where the limb enters the bag avoids constriction that could impede circulation within the limb.

The Controlled Environment Treatment Unit consists of three basic parts: an air-control console, an interconnecting flexible hose, and a dressing bag (9,10,22). Filtered air is used as a dressing medium and timed cycles of alternating high and low air pressure are used according to a preset program under the operator's control. The amputation wound, together with its controlled environment, is housed within the transparent polyvinyl chloride (PVC) bag. Bag position is maintained with a lightweight webbed harness anchored about the waist.



Equipment in the air control console (Fig. 2) includes several stages of centrifugal air compression, several stages of air filtration, provision for temperature and humidity control, and the valves and timing mechanisms needed to regulate the magnitude and duration of pressure phases (9,10,22). The controls allow the operator to preset a cycle with alternating high and low pressure phases: pressures available are anywhere from 10 to 50 mm Hg, and phase durations from 0 to 5 minutes are available.

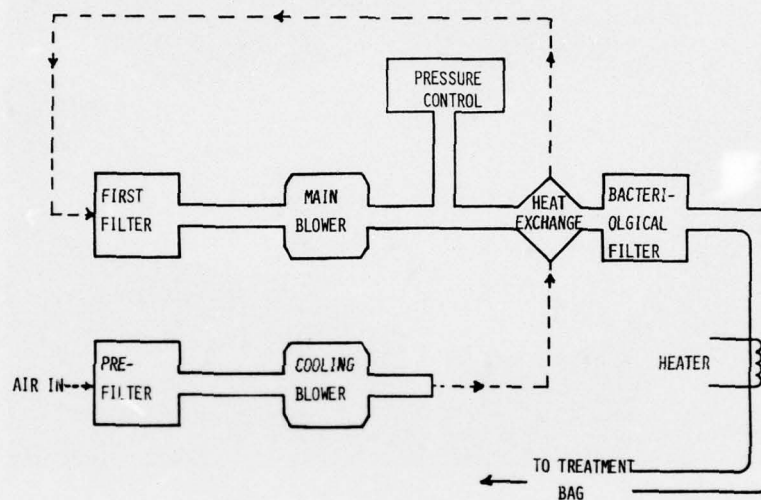


FIGURE 2. - Diagram of air flow system for CET.

Following final compression, air is cooled and blown through a high-efficiency filter capable of 99.998 percent retention of particles of  $0.6 \mu$  or greater, thus providing sterility. The filtered air is then passed over a heating element and raised to a preset temperature. Temperature may be varied in a range from approximately 4 deg Celsius above ambient room temperature to 40 deg Celsius (3 deg above body temperature). Three separate thermal cutouts are incorporated to switch off the heater in the event that air temperature rises too high. This fail-safe feature is automatic and will reset after the temperature returns to normal limits. Since air is cooled and re-warmed before delivery to the amputation site (Fig. 2), relative humidity is reduced, providing dry conditions within the dressing bag.

Once heated to the desired temperature, the processed air travels through a length of flexible hose to a presterilized, pliable, transparent treatment bag enclosing the residual limb or other part to be treated (Fig. 3). The hose allows convenient placement of the machinery near the patient's bed, and permits the patient to sit, or to stand beside the bed, or even to walk a few steps on the remaining foot with the aid of crutches or a walker.

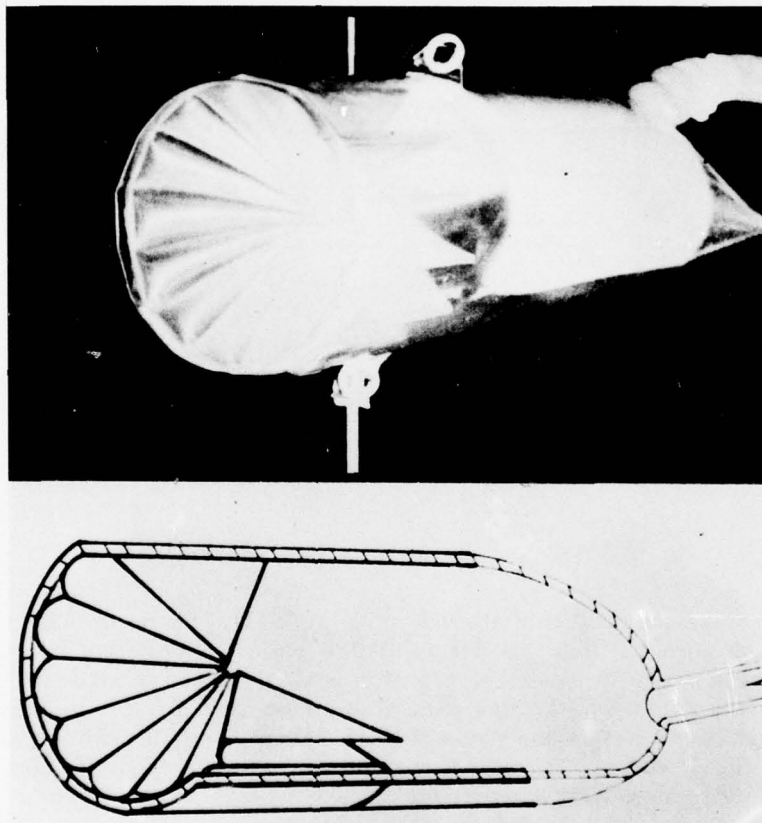


FIGURE 3. — CET polyvinyl chloride treatment bag illustrating cross sectional and full view of proximal "flutter" seal.

#### Burgess and Pedegana: Controlled Environment Treatment

Construction of this transparent, flexible yet tough dressing allows visual inspection and palpation of the wound through the bag. A thin pad supports the limb, but there is no rigid support for contouring.

A flexible, pleated seal at the proximal end of the bag maintains the preset pressure within the chamber regardless of limb volume changes and without the risk of a tourniquet effect, i.e., pressure from the seal around the thigh is generated only by the air pressure inflating the pleats, so seal pressure never exceeds that within the bag (22). (The seal is a modification of the Hovercraft® principle.) In addition, the seal's "flutter" system provides a continuous but slow escape of air, which serves to cool and to ventilate the wound environment. Because of the positive pressure within the treatment bag, and the gradient through the seal about the thigh to the atmosphere, only the warm, sterile air introduced is present. Unsterile air cannot gain entry against the pressure gradient and low flow rate through the nominally open proximal end (23). Consequently, risk of environmentally induced infection is minimal.

Bag design has been patented by the British Medical Research Council. Variations in types and sizes of treatment bags, including a body surface or trunk "barnacle" dressing, are being studied at Roehampton and will be made available as needed.

#### APPLICATION OF CET

The CET unit used in the initial study is designated Mk I. It was a large, heavy, moderately noisy, yet easily constructed device which allowed convenient access to its internal machinery for repair and modification. As an evaluation prototype it has served its purpose well. An improved, more compact device, CET Mk II (Fig. 4), is currently being used, and other variants are described below.

Treatment of the first 20 amputee patients was initiated immediately following below-knee surgery and was continued for an average of 10 postoperative days. During that time wound healing progress, incidence of infection and hematoma, degree of any limb edema, requirements for pain medication, and patient activity were clinically observed. The drain, when used, was removed with a sterile forceps through the proximal opening and seal of the dressing bag, normally within 72 hours following surgery. Upon completion of Controlled Environment Treatment, the residual limb was routinely fitted with an Immediate Postsurgical Prosthesis and carried on through the routine rigid dressing technique to definitive limb fitting.



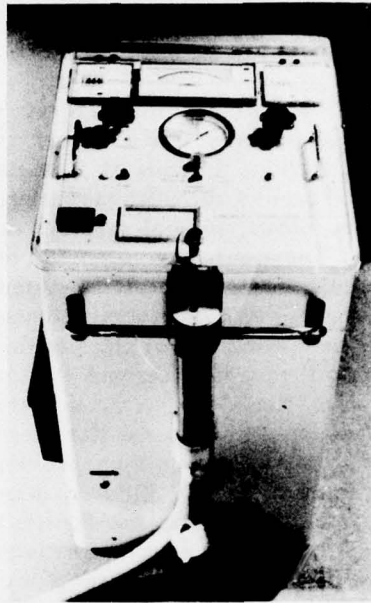


FIGURE 4. — Improved console (Mk II) now in use.

#### **Pressures, Cycle Times, and Temperature Settings**

Pressures, cycle times, and temperature were set within ranges recommended by the Biomechanical Research and Development Unit, Roehampton, England (9,10). The initial 12 cases managed with CET were on a regimen with high pressure ranging from 45 to 50 mm Hg for 30 s, and low pressure set at 10 mm Hg for 60 to 90 s. In several instances, the high pressure setting was reduced on or about the 7th postoperative day. The last eight cases in this study were managed with a somewhat reduced high pressure phase: in those cases, the high pressure phase was applied at 30 mm Hg for 30 s, and low pressure was set at 10 mm Hg for 60 to 90 s. Temperature was set at 38 deg Celsius for the first 12 cases, and reduced to 32 deg Celsius for the last 8 cases. Patients appeared to be more comfortable at the lower temperature.

The relatively arbitrary pressure, time, and temperature parameters were based on clinical and experimental observations relative to dynamic limb blood flow. Ischemic limbs coming to amputation have only one common and absolute characteristic, i.e., the need to amputate. Individual variations in limb blood flow and limb hemo-



dynamics vary from patient to patient in different pathological states. The treatment protocol was designed with sufficient latitude of safety neither to harm nor to delay the wound healing process.

Adjustments to pressures and cycle times were in many instances made partially on the basis of patient comfort. For example, the trial use of cycle with a 10-s low pressure phase produced noticeable discomfort in cases with both normal and impaired vascularity. We currently use a program of approximately 30 mm Hg for 30 s on high pressure, and 10 mm Hg for 30 to 90 s on low pressure. Basic research on cycle pressure/time relationships is currently a subject of investigation at our center (13,17). It is possible that more flexible treatment regimens will result from these studies.

#### **EXPERIENCE ON FIRST 20 CASES**

The 20 below-knee amputation surgeries here reported were all treated by the Prosthetics Research Study staff at the Veterans Administration Hospital, Seattle, Washington. Consecutive below-knee amputations, regardless of etiology, were placed in the machine whenever it was available. Cases were not randomized nor was a control group used, although the patient population could be compared with an experience of several hundred below-knee amputations at this single hospital for similar pathologies.

Patient population consisted of all males, ranging in age from 25 to 85 years (Table 1). Nine patients, or 45 percent, had peripheral vascular disease with diabetes; another 7 (35 percent) underwent amputation for peripheral vascular disease without diabetes; and in the remaining 4 cases (20 percent) posttraumatic complications was the primary reason for amputation (Fig. 5).

Eighteen patients in this study were unilateral amputees, two were bilateral. Both bilateral patients were amputated for peripheral vascular disease, one with diabetes and one without. All 20 cases involved primary wound closure with or without drainage. The standard long posterior myocutaneous flap was utilized in all instances except one in which the flap was irregularly fashioned due to skin loss from the original trauma.

#### **Wound Healing Progress**

Eighteen patients (90 percent) healed promptly and without incident at the below-knee level. The two cases which required revision to the above-knee level failed to heal due to ischemic skin and muscle necrosis. This diagnosis was confirmed in both cases by tissue examination and culture. No infection was present in either patient.

TABLE 1

Patient Number	Age	Etiology	Drain	Hematoma	Type of medication	Pain medication										Revision to AK	Cast and measurements	
						Days of medication												
						0	1	2	3	4	5	6	7	8	9	10		
1	58	PVD	Yes	No	Ascriptin-oral					X	X	X	X	X	X	X	No	39 POD
2	53	PVD	No	No	Demerol-injected Demerol-oral Phenergan-injected	X	X	X		X	X	X					No	38 POD
3	84	PVD with diabetes	Yes	No	Demerol-injected Phenergan-injected Darvon-oral	X										X	No	None
4	85	PVD	No	No	Demerol-injected Phenergan-injected Codeine-oral Codeine-injected	X	X	X	X								Yes	45 POD (Post AK Rev.)
5	53	Trauma	Yes	No	Demerol-injected Phenergan-injected Tylenol-oral	X	X								X	X	No	39 POD
6	82	Trauma with PVD	Yes	No	Demerol-injected Phenergan-injected Ascriptin	X	X								X	X	No	34 POD
7	25	Trauma	No	No	Demerol-injected Percodan-oral Codeine-oral	X	X	X	X								No	60 POD

Burgess and Pedegana: Controlled Environment Treatment

TABLE 1

Patient Number	Age	Etiology	Drain	Hematoma	Type of medication	Pain medication											Revision to AK	Cast and measurements
						0	1	2	3	4	5	6	7	8	9	10		
8	70	PVD	No	No	Demerol-injected Demerol-oral Codeine-oral	X		X	X	X							Yes	Expired 51 POD
9	85	PVD with diabetes	No	No	Demerol-injected Demerol-oral	X	X	X	X	X	X	X	X	X	X	X	No	41 POD
10	62	PVD with diabetes	No	No	Demerol-injected Codeine-oral	X	X					X					No	35 POD
11	59	PVD with diabetes	No	No	Morphine-injected Codeine-oral	X	X										No	41 POD
12	59	PVD with diabetes	Yes	No	Morphine-injected	X	X										No	70 POD
13	40	PVD with diabetes	Yes	No	Morphine-injected	X	X	X	X	X							No	46 POD
14	62	PVD	No	No	Demerol-injected Demerol-oral	X	X	X	X								No	36 POD
15	33	Trauma	No	Yes	Percodan-oral Demerol-injected Tylenol-oral	X	X	X	X	X	X						No	41 POD



TABLE I

Patient Number	Age	Etiology	Drain	Hematoma	Type of medication	Pain medication											Revision to AK	Cast and measurements
						0	1	2	3	4	5	6	7	8	9	10		
16	85	PVD with diabetes	Yes	No	Percodan-oral	X	X										No	39 POD
17	58	PVD	Yes	No	Demerol-injected Talwin-oral	X	X	X	X	X	X	X	X	X	X		No	65 POD
18 <sup>a</sup>	58	PVD	Yes	No	Morphine-injected Codeine-oral Tylenol-oral	X	X	X	X	X	X	X	X	X	X	X	No	33 POD
19	58	PVD with diabetes	Yes	Yes	Demerol-injected Phenergan-injected Percodan-oral	X	X	X	X	X	X	X	X	X	X		No	39 POD
20 <sup>a</sup>	63	PVD with diabetes	Yes	No	Demerol-injected Phenergan-injected Codeine-oral	X	X										No	None

<sup>a</sup> Bilateral below-knee amputees.

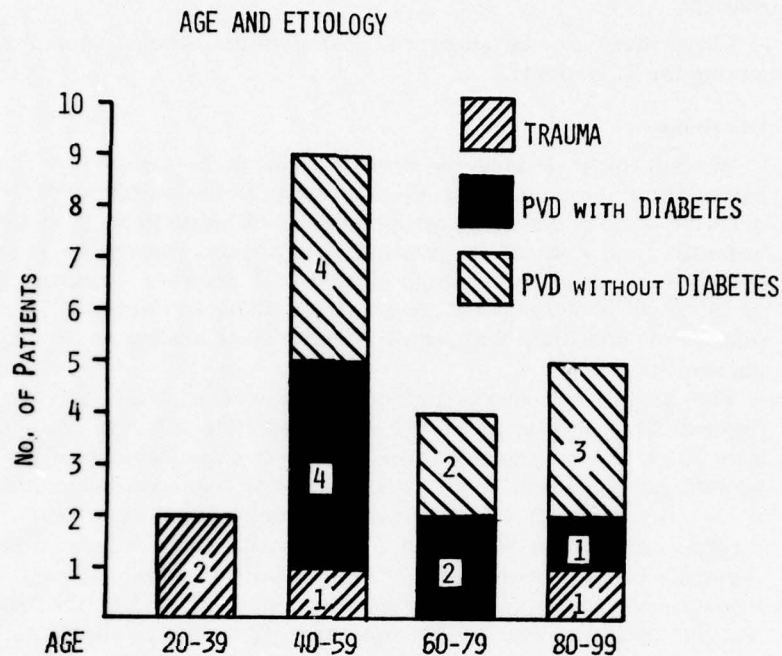


FIGURE 5. — Chart depicting age and etiology of 20 patients.

In addition to the two patients who required revision to the above-knee level, there was one instance of mild wound separation at the suture line with delay in healing. This individual, a 59-year-old male with peripheral vascular disease and diabetes, had previously been treated by bilateral aortofemoral and femoral-popliteal Dacron grafts. The below-knee amputation was healing uneventfully at the time of the patient's removal from the CET unit and application of the first cast, which was on the 12th postoperative day. At the time of the second cast application, the 26th postoperative day, it was noted that the skin was overlapped and that a small area of skin necrosis had occurred at the suture line. No additional surgery was necessary, and the patient proceeded to uneventful wound healing without infection. He was fitted with a definitive prosthesis on the 70th postoperative day with subsequent completion of his rehabilitation.

#### Infection

There were no instances of postoperative wound infection among the 20 patients.

#### Hematoma

Wounds were drained by Penrose drain in 55 percent of the cases. There were two instances of postoperative hematoma. One occurred during the first postoperative week subsequent to drain removal, in a case of amputation for chronic, gangrenous foot ulcers with peripheral vascular disease and diabetes. Occurrence of the small hematoma was, in our opinion, due to improper drain placement. The drain was removed and wound healing progressed uneventfully.

The second hematoma occurred in a wound which was not drained. This patient presented with a severely infected crushed right foot. An emergency open guillotine amputation was performed just proximal to the ankle and was managed postoperatively with CET. A closed below-knee amputation revision was carried out 10 days later, also followed with CET. A hematoma occurred on the second day after definitive amputation; two sutures were removed, the hematoma evacuated, and a new bag was put in place. The wound subsequently healed promptly and without further difficulty, and the patient progressed rapidly to full rehabilitation.

#### Edema Control

The CET was noticeably effective in controlling postoperative residual limb edema. In all 20 cases, edema was felt to be absent or significantly reduced from the preoperative state. A number of photographic methods were used to measure edema, and we are currently in the process of refining a technique to quantitate residual limb volume changes during Controlled Environment Treatment. This technique, which makes use of a small strain gage sutured adjacent to the operative site, was used in conjunction with CET in 4 of the 20 cases.<sup>b</sup> This system of instrumentation is based upon the hypothesis that skin tension adjacent to the suture line is related to limb volume (7). With the feasibility phase of this method now completed, it is expected that CET

<sup>b</sup> See paper entitled, "A Proposed Technique for the Postoperative Monitoring of Skin Tension in Below-Knee Amputees," by E. M. Burgess, M.D., Craig A. Spolek, M.S., and A. James Moore, as presented elsewhere in this issue of the BPR. (Three of the four cases are described in detail. Data on the fourth, and on four others, were invalidated by various mechanical difficulties).



efficacy in edema control can be quantitatively demonstrated with more accuracy in the future.

#### Pain

In general, patients were remarkably comfortable during CET. The amount of pain medication was monitored (Fig. 6). It is interesting to note that one patient required only aspirin following amputation. The majority of patients did not require injectable pain medication after the first postoperative day and took no oral narcotics after the fourth postoperative day. More frequent and extended use of injectable or oral narcotics was required in a few cases where there had been a previous history of drug abuse or excessive preoperative pain medication. One patient who developed a hematoma required larger amounts of pain medication until the hematoma was evacuated. Diabetic patients appeared to experience less postoperative discomfort than others in this series.

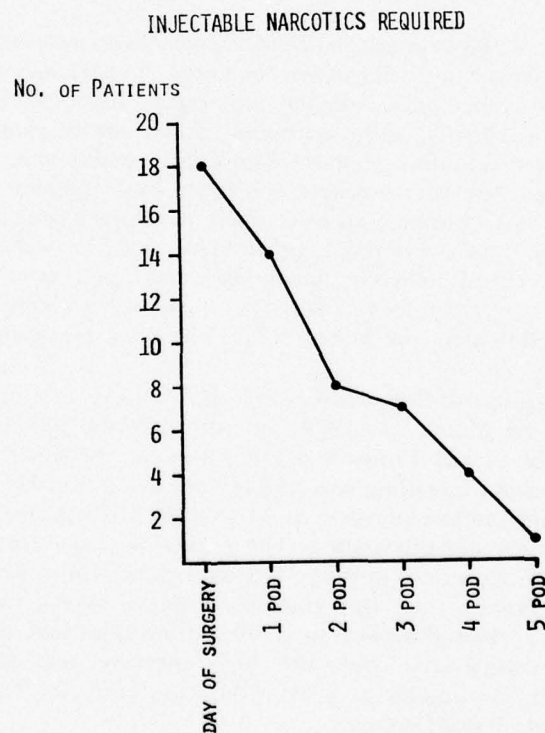


FIGURE 6. — Injectable narcotics required for the first five postoperative days. Two patients did not require injectable narcotics.

#### Time from Surgery to Definitive Prosthetic Prescription

Sixteen of the patients were successfully cast and measured for a definitive below-knee prosthesis. The average time from surgery to cast and measurements for a definitive prosthesis was 43 days; of the 16 patients fitted, 12 averaged 37 postoperative days. Average time was relatively the same in all three etiological groups.

Of the four additional patients, one was discharged to a nursing home on a non-ambulatory basis with the below-knee amputation well healed (this patient had been non-ambulatory for more than 1 year prior to admission and had a severe left hemiparesis). Another patient expired from myocardial infarction before completion of his rehabilitation; a third patient (a bilateral amputee) was, because of associated disabilities, not included in the routine post-operative rehabilitation protocol; and the fourth patient was successfully fitted following revision to the above-knee level.

#### Case Studies

*Case No. 1:* 58-year-old male with severe arteriosclerosis without diabetes. Associated diagnoses included hypertension, cardiac hypertrophy, glaucoma, arrested pulmonary tuberculosis, chronic rheumatoid arthritis, and carcinoma of the larynx (postsurgical). In 1972 a cross-pubic (femoral-femoral) vascular vein graft was placed in an attempt to relieve left lower limb ischemia. Pain was decreased, but chronic ischemic ulcers developed over the lateral aspect of the distal left foot, and the lateral three toes were amputated. Superficial ischemic ulcers also developed over the distal dorsum of the right foot. The patient had not walked for 1 year prior to admission on March 13, 1974 for amputation of the left leg (Fig. 7).

A long-posterior-flap, closed, left below-knee amputation was performed on March 15, 1974, and the residual limb was placed immediately in the Controlled Environment Treatment chamber. The high pressure reading was initially set at 50 mm Hg for a 30 s interval, and the low pressure at 11 mm Hg for 120 s interval, with the pressure states alternating. The patient was comfortable post-operatively, requiring nothing but salicylates for relief of pain. The low pressure state was gradually reduced over a 3-day period from 120 s time duration to a 60 s time duration, and on the seventh postoperative day the high pressure was reduced to 37 mm Hg continuing at a 30 s duration (Fig. 8). Temperature remained at 30 deg Celsius.

Healing progressed uneventfully; the patient remained afebrile, comfortable, and without demonstrable evidence of residual limb



FIGURE 7. — Case No. 1: Preoperative view of failed vascular reconstructed patient.



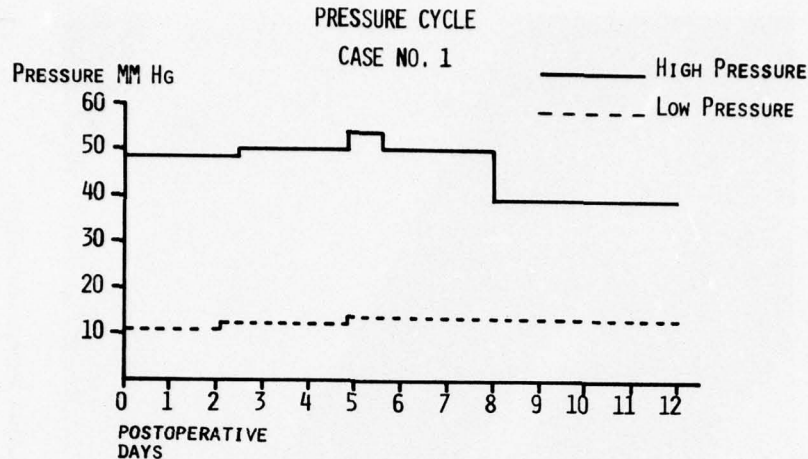


FIGURE 8. — Case No. 1: Pressure cycle during CET.

edema. On the 14th postoperative day the limb was removed from the CET unit and placed in a plaster of paris rigid Immediate Postoperative type of prosthetic dressing. Assisted ambulation with touchdown was then initiated, and weightbearing was gradually increased according to tolerance. Sutures were removed on the 27th postoperative day with firm primary healing of the operative wound (Fig. 9).

The patient was measured and cast for a definitive prosthesis on the 39th postoperative day. After it was delivered, he was discharged from the hospital (Fig. 10), walking independently with his prosthesis and walkerette. At this time, the superficial ulcers on the right foot had healed.

Two years following amputation, he continues wearing his prosthesis daily, ambulatory with external aids, and living at home. No other surgical treatment has been required for ischemia of his lower limbs.

*Case No. 2* (Case No. 5 on Table 1): 53-year-old male who had sustained severe compound fractures of the right distal tibia and fibula, secondary to missile wounds incurred in 1945. Chronic osteomyelitis of the distal tibia developed, requiring 2½ years of hospitalization and approximately 15 open surgical procedures. Fracture union was achieved but there was a 3 in leg length discrepancy, with a spontaneous arthrodesis of the ankle and limited motion throughout the tarsal and toe joints. The foot was fixed



FIGURE 9. — Case No. 1: Four weeks following surgery.



FIGURE 10. — Case No. 1: Patient in definitive prosthesis after completion of rehabilitative care.



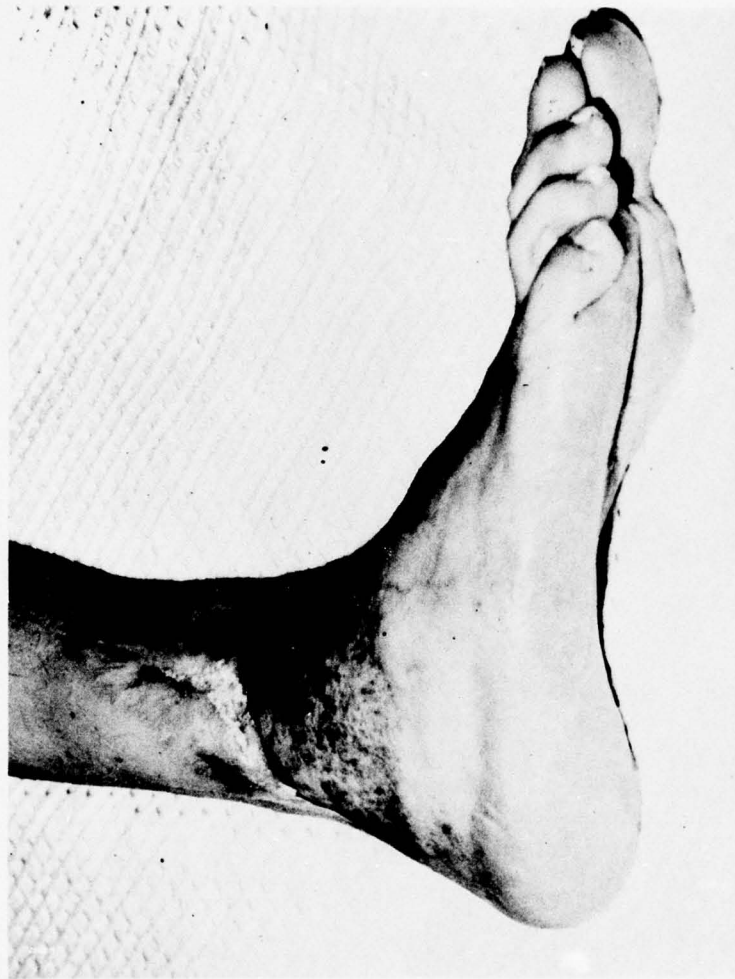


FIGURE 11. — Case No. 2: Preoperative view of patient with longstanding osteomyelitis.

in varus, and moderate hypesthesia and motor dysfunction secondary to scarring were present (Fig. 11). An orthopedic shoe and brace had been required for many years, and the patient experienced pain on weightbearing.

He was admitted to the Seattle Veterans Administration Hospital on May 8, 1974, for the treatment of an acute flareup of the osteomyelitis, demonstrated by drainage, fever, chills, regional lymph adenopathy, and elevated white count and sedimentation rate.



FIGURE 12. — Case No. 2: Residual limb in CET immediately following surgery.

It was decided, after control of the systemic aspects of the infection, to proceed with amputation.

On May 10, 1974, a closed below-knee amputation was performed above the site of the draining osteomyelitis. The patient was placed immediately after surgery in the CET unit (Fig. 12).

#### Burgess and Pedegana: Controlled Environment Treatment

Pressures were set at 50 mm Hg for 30 s and 10 mm Hg for 50 s, alternating with the temperature set at 30 deg Celsius (Fig. 13). The drain placed at surgery was removed on the first postoperative day, and the patient was allowed up in a chair.

Preoperatively, 50 mg of Demerol and 25 mg of Phenergan by intramuscular injection had been required for pain control. The patient was kept on this medication for one postoperative day, but at the end of the second postoperative day, only an occasional oral analgesic was needed. No edema developed; the patient was allowed in a walkerette with the CET chamber in place, and no local or systemic evidence of infection followed the amputation.

Six days following amputation, because of the patient's rapid and excellent progress, his leg was removed from the CET chamber and placed in an immediate postsurgical prosthetic cast. He was discharged from the hospital, ambulatory on crutches, the following day.

Healing progressed uneventfully (Fig. 14), the definitive prosthesis was delivered and fitted on the 39th postoperative day, and he has become a successful, fully rehabilitated amputee, requiring no external aids and carrying out essentially a normal social and work life.

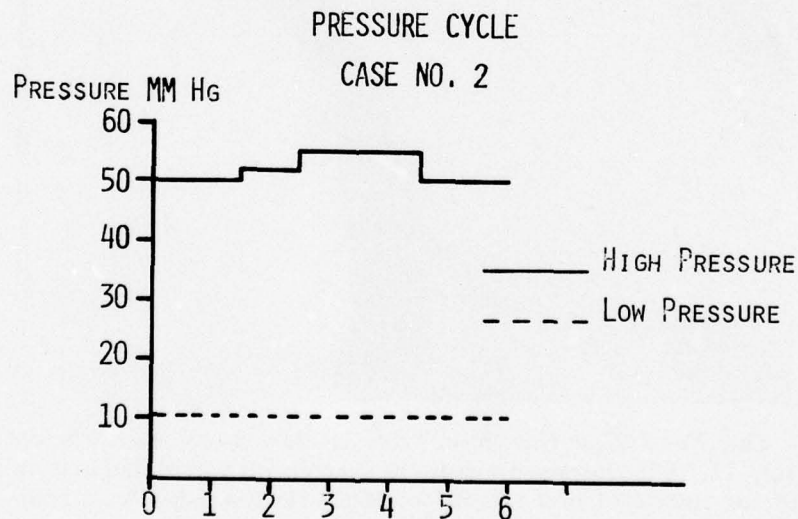


FIGURE 13. - Case No. 2: Pressure cycle during CET.





FIGURE 14. — Case No. 2: Residual limb following removal from CET, shown at 12 days post-surgery.

*Case No. 3* (Case No. 15 on Table 1): 33-year-old male, who on July 15, 1975, sustained a crushing injury with partial amputation of his right foot in a railroad accident. He was taken to a community hospital, where a debridement was carried out on the day of injury and the amputation site closed at a transmetatarsal level.



FIGURE 15. — Case No. 3: Guillotine amputation for severe sepsis, prior to definitive below-knee amputation.

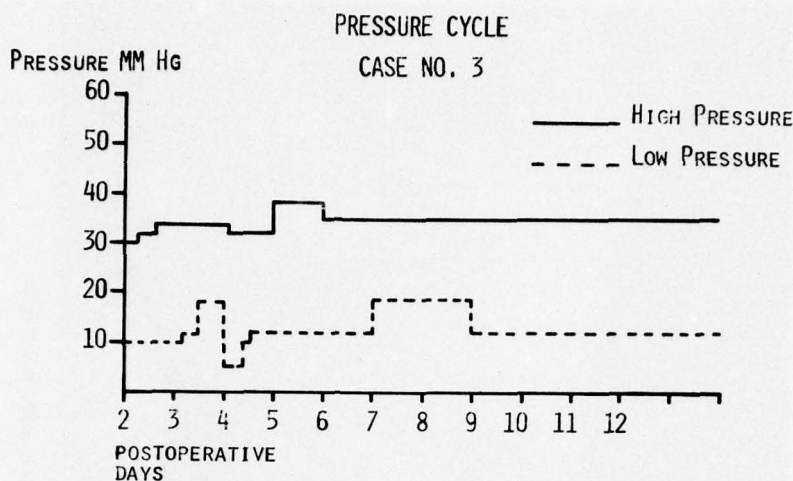


FIGURE 16. — Case No. 3: Pressure cycle during CET.

Severe infection with septicemia developed; the patient was transferred to the Seattle Veterans Administration Hospital, and on July 20, 1975, an emergency open amputation was performed just above the ankle joint to control infection (Fig. 15). Soft dressings were applied. Two days following amputation, the limb was placed in the CET bag with pressure readings at 30 mm Hg for 30 s on high and 10 mm Hg for 60 s on low, with the temperature set at 32 deg Celsius (Fig. 16). Local and systemic signs of infection were promptly controlled; pain moderated rapidly.

Ten days following the guillotine amputation, a closed below-knee amputation 18 cm in length was performed, using a long posterior flap. No drain was placed because the wound was dry after hemostasis and release of the tourniquet. The residual limb was again placed in the CET chamber, with pressure gradients set at the same levels as previously. On the second postoperative day, a hematoma developed. The limb was removed from the chamber, two sutures were removed, the hematoma evacuated, and the limb replaced in the CET. The patient then continued to heal uneventfully with rapid elimination of the edema present at the time of surgery and with a comfortable postoperative course. A strain gage had been applied at the suture line at the time of closure. This was not disturbed, and continuous readings, indicating tissue tension, were taken.

Nine days following amputation, the leg was removed from the CET chamber. Healing was progressing well without infection,





FIGURE 17. - Case No. 3: Residual limb three weeks following surgery.

edema, or evidence of necrosis or wound disruption (Fig. 17). Further rehabilitation progressed uneventfully with the rigid dressing technique.

A cast and measurement were taken for a definitive prosthesis 41 days following amputation. Amputee rehabilitation proceeded uneventfully to an excellent functional result.

*Case No. 4:* 85-year-old male, admitted to Seattle Veterans Administration Hospital on March 25, 1974, with severe peripheral vascular disease, ischemia of the lower limbs, and gross edema (Fig. 18). Associated diagnoses were generalized arteriosclerotic cardiovascular disease, congestive heart failure, and severe anemia.

The chief complaint involving the lower limbs was severe rest pain in the right foot, increasing over a 3-year period. The patient required daily nitroglycerin for control of angina. Four weeks of medical supervision were necessary after admittance to prepare the patient sufficiently to withstand a below-knee amputation. This surgery was performed on April 23, 1974, using the classical long posterior flap technique. The wound was not drained; CET



FIGURE 18. — Case No. 4: Preoperative appearance of patient with severe peripheral vascular disease.

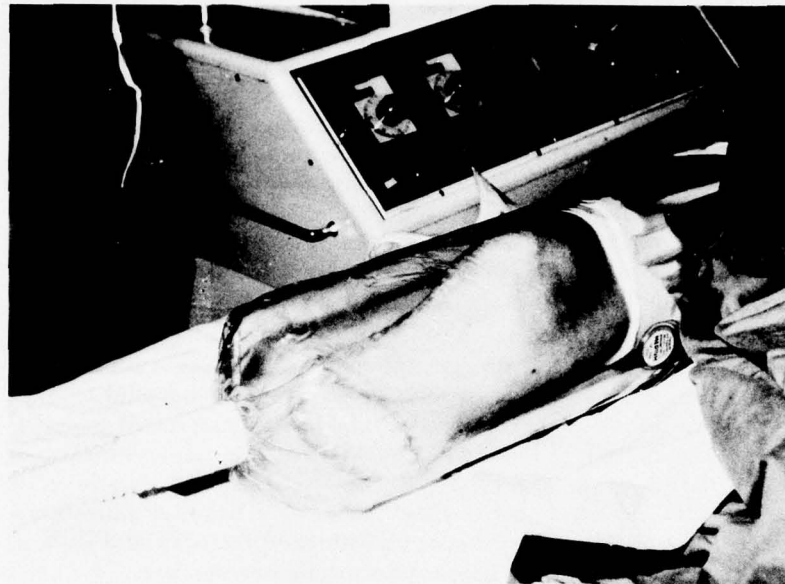


FIGURE 19. — Case No. 4: Residual limb in CET immediately following surgery.

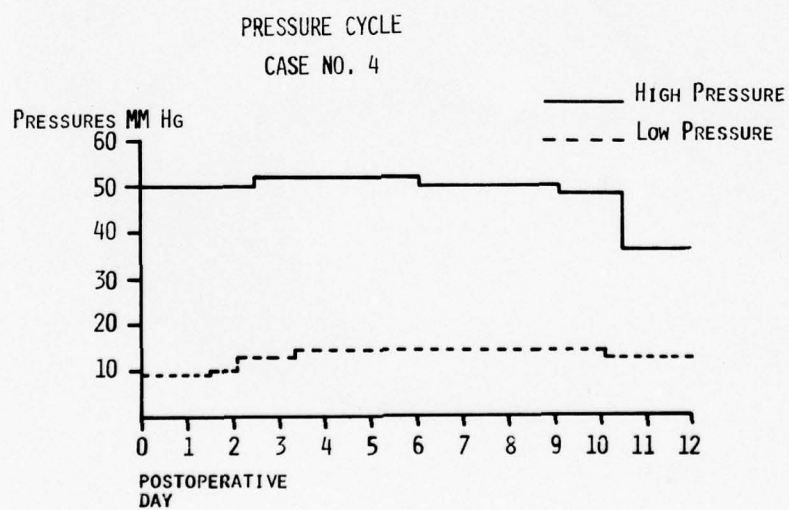


FIGURE 20. — Case No. 4: Pressure cycle during CET.



was initiated immediately (Fig. 19) with a high pressure reading at 50 mm Hg for 30 s, and low pressure at 10 mm Hg for 50 s, alternating, and with the temperature at 38 deg Celsius (Fig. 20).

Pain was minimal; the patient moved the leg comfortably within the chamber, but on the second postoperative day, he experienced increasing substernal chest pain and shortness of breath, and developed a recurrence of congestive heart failure. His cardiovascular status, including chest pain, was improved by further active medical treatment, but the below-knee amputation site did not heal (Fig. 21); marginal skin necrosis developed, and it was necessary to revise the amputation to the above-knee level 17 days following the initial surgery.

A rigid dressing was applied, tilt table positioning was gradually instituted, and the patient was discharged from the hospital 15 days following the above-knee amputation. Healing progressed uneventfully (Fig. 22) and 30 days later, the patient was cast and measured for a definitive prosthesis. He continues to use the prosthesis at home with a walker and has had no further hospital admissions. He is ambulant for short distances with the prosthesis and walker, lives with his family, and requires no special nursing care.

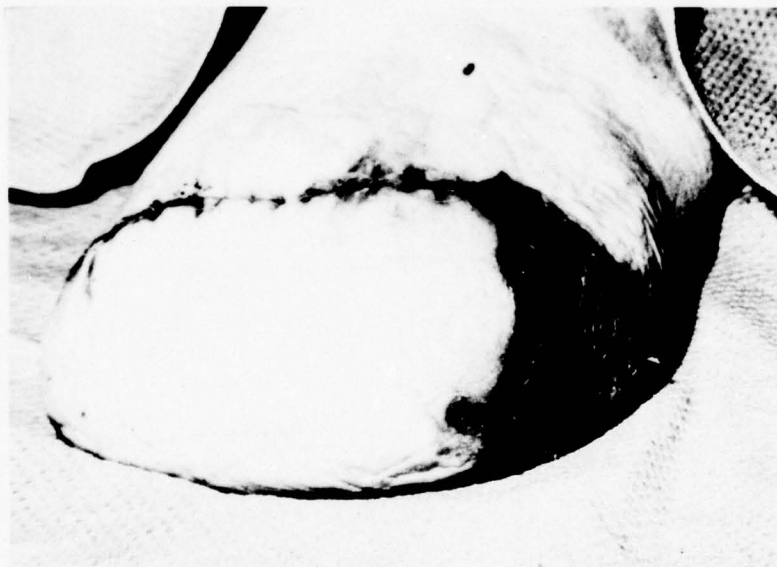


FIGURE 21. — Case No. 4: Residual limb 17 days following amputation. Dry ischemia and gangrene present, with no evidence of edema, cellulitis or infection.



FIGURE 22. — Case No. 4: Completely healed above-knee amputation.

At the time of the above-knee amputation, the below-knee site was studied. There was no infection present; the failure in healing was due to ischemia. This elderly patient was considered a failure in pre-operative level determination. He would normally have had an above-knee amputation initially; however, an attempt was made to salvage the knee since he had been ambulatory prior to hospitalization. Judgment as to rehabilitation potential was, however, verified by the fact that 1 yr following the amputation, he was walking with an above-knee prosthesis and living at home. This case represented one of two healing failures, neither of which can be attributed to the CET physical environment.

#### CET Mk II UNIT

Following initial clinical trials at Roehampton and Seattle, a smaller, lighter-weight, and quieter version of the CET was constructed. This unit, designated Mk II (Fig. 4), provides easier operation and control. Of paramount importance is the replacement of the deadweight pressure regulator system with a gas-regulated

method. Simple adjustments in pressure, temperature, and cycle times can be made with controls conveniently located in the front panel. The Mk II unit is now standardized equipment, available commercially (through the Cape Engineering Company Limited, Warwick, England) as the Cape Sterishield Controlled Environment Treatment System®.

#### Capabilities of Equipment

1. Pressure — 0–50 mm Hg, constant pressure or alternating cycles of high and low pressure.
2. Cycle Time — constant pressure, or a cycle made up of two alternating periods, each of which may be set at 0–300 s (Mk I) or 0–999 (Mk II).
3. Temperature — from approximately 4 deg Celsius above ambient room temperature to 40 deg Celsius (3 deg above body temperature).
4. Sterility — HEPA bacterial filter (99.998 percent efficiency on 0.6  $\mu$ m particles).
5. Humidity — provides reduced relative humidity (air is cooled and rewarmed prior to entering the treatment bag).
6. Gas Composition — room air is routinely used; however gas composition may be altered by introduction of other gas; e.g., O<sub>2</sub>.

#### DEVELOPMENT OF RELATED MANAGEMENT SYSTEMS

The clinical application of CET has provided impetus for the development of related management systems. These units supply elevated air pressure for control of edema states which do not require a sterile environment. Compared with CET, they cost and weigh less and are more compact.

First to design a related system was the Biomechanical Research and Development Unit (BRADU), Roehampton, England. Their Pressure Environment Treatment (PET), incorporates all features of the CET, with the exception of sterility and temperature controls. The PRS system, Modulated Air Controlled Environment (MACE), has basically the same capabilities as the PET, with slightly different treatment ranges and methods of adjustment. Both the PET and the MACE employ the CET dressing bag.

A third unit, the Rancho Edema Control System, developed at the Rancho Los Amigos Hospital, employs a doughnut-shaped seal in its treatment bag. This seal, inflated to only three-quarters of the pressure in the bag, is intended to avoid constriction but to



TABLE 2. - Comparison of Types of Equipment

	Mk II CET (Sterishield)	PET	Mk II MACE	Rancho Edema Control System
Cost (approx.)	\$5,000-\$6,000	\$2,500-\$3,500	\$1,200	\$1,500
Size	18 x 26 x 35 in. (9.5 ft <sup>3</sup> )	18 x 26 x 20 in. (5.4 ft <sup>3</sup> )	10 x 16 x 13 in. (1.2 ft <sup>3</sup> )	10 x 17 x 11 in. (1.1 ft <sup>3</sup> )
Weight	154 lb	100 lb (approx.)	25-35 lb	15 lb
Pressure	0-50 mm Hg Externally adjustable	0-50 mm Hg Internally adjustable	High pressure externally selected for 20, 30, 40 mm Hg or higher; low pressure 10 mm Hg internally adjustable	0-30 mm Hg Externally adjustable (no pressure feedback)
Cycle time	Continuous or alternating; 0-999 s high and low pres- sure	Alternating high and low pressure 0-300 s	Continuous or alternating high and/or low pressure 30, 60, 90 s	Continuous
Temperature control	Yes	No	No	No
Sterility	Yes	No	No	No
Seal	CET	CET	CET	"Doughnut" type; seal pressure 75% of bag (set) pressure

allow slow leakage from the bag. Unlike the CET, PET, and MACE, the Rancho System provides constant pressure only. A comparative summary of these treatment systems is seen in Table 2.

#### CET TRIAL CENTER REPORTS

##### *San Francisco VA Hospital; Wesley S. Moore, M.D.*

As of February 25, 1977, 8 patients had been managed with CET. Five of these cases were part of a controlled and randomized study of lower-limb amputations in which CET is being compared with the Immediate Postsurgical Prosthetic Fitting Technique. Three additional cases of venous stasis ulcers were treated with the device, and results were encouraging.

Dr. Moore will report his findings in a separate publication upon completion of a larger number of cases. At this time, he remains enthusiastic about CET; however he is not yet in a position to measure the advantages or disadvantages in wound healing with either *method of postoperative management*. His program using CET is ongoing, carefully ordered in a scientific statistical manner, and requires more time before additional conclusions can be drawn.

Dr. Moore was appointed Professor and Head, Section of Vascular Surgery, The University of Arizona Health Sciences Center, College of Medicine, Department of Surgery, Tucson, Arizona, and will serve as a consultant to the VAH, Tucson, Arizona.

##### *Rancho Los Amigos Hospital; Downey, California, F. William Wagner, Jr., M.D.*

Between March 1, 1975 and March 31, 1976, CET was used in the postsurgical management of the first stage of 13 two-stage Syme's amputations, performed for diabetic and dysvascular infection and gangrene. A control group, comprising 41 patients, used a bias-cut stocking as the method of postoperative treatment. Average age of combined cases completed during this time period was 60.4 years.

Dr. Wagner reported a 62 percent wound healing success in the trial (CET) group and a 73 percent success in the control group. He feels that at this time it is not possible to determine the advantages or disadvantages of CET, as it relates to wound healing progress, compared to conventional wound management systems.

Dr. Wagner is, however, interested in the use of CET as a therapeutic tool, he has suggested monitoring tissue levels of antibiotics to determine the efficacy of the equipment in management of infection prior to proposed amputation. Rancho Los Amigos Hospital has submitted a grant request for a wound healing study using CET.

#### **Burgess and Pedegana: Controlled Environment Treatment**

Additional cases involving the use of CET at this facility have included treatment of edema states of the lower limbs, vascular ulcers, and well-draining infections (primarily in the ischemic limb). At this time, the Rancho Edema Control System, developed under Veterans Administration financing and sponsorship, is being used as well in treatment of edema states which do not necessarily require a sterile environment.

*Castle Point, New York, VA Hospital: Bok Y. Lee, M.D., Frieda S. Trainor, Ph.D., and David Kavner, Ph.D.*

During a 15 month trial period, which began in December 1974, CET was used in below-knee and distal amputations (3 cases) and in the management of ischemic ulcers (3 cases). Overall experience has been positive, and CET has been incorporated into the treatment armamentarium of the Vascular-Surgical Service at Castle Point.

This facility continues to use the equipment and is satisfied with the technique, particularly in control of edema and in the treatment of circulatory and static ulcers of the lower limb. A major interest of this project is prevention of amputation in dysvascular patients. Because of the low amputation rate at Castle Point VA Hospital (3 to 5 yearly), CET is primarily being used in the management of ischemic ulcers, with emphasis on studying the effect of CET on compartmental fluid distribution, venous pumping, and skin blood flow.

*Duke University Medical Center, Durham, North Carolina: James R. Urbaniak, M.D., and Frank W. Clippinger, Jr., M.D.*

CET has been used at this facility for the treatment of upper and lower limb edema states and for the postsurgical management of hand trauma and hand reconstructive surgery. Between January 1975 and January 1976, 9 cases were managed with CET, including 8 hand pathologies (of which 4 were replantation procedures) and 1 case of posttraumatic edema of the lower limb. Because it was not possible to include suitable controls in their study, the clinical trials at Duke University Medical Center were essentially a field study, consisting of carefully documented case reports.

Their results to date have been encouraging in the areas of application. The staff at Duke have found the equipment to be a most valuable clinical asset in the treatment of acute and chronic edema states, and they have suggested further long range use of the device to determine the efficacy of CET in wound healing. Following initial clinical trials, longer treatment bags to provide elbow support were requested and supplied to this facility; additional suggested modifications included a banana-shaped dressing bag to accommo-



date a flexed elbow.

This facility plans to continue incorporation of CET into the care of postsurgical and posttraumatic hand problems and, at present, is investigating use of the equipment for edema states which do not necessitate a sterile environment. Hence, the simpler management systems (PET, MACE, and Rancho Edema Control System) would be helpful in these situations.

*Prosthetics Research Study, Seattle, Washington: Ernest M. Burgess, M.D.*

The CET Technique was used by the Prosthetics Research Study for a period of approximately 3 years, treating lower-limb amputations immediately postsurgically.

The original upper-limb dressing bags were too short. Modified bags have since been constructed to accommodate the entire arm up to the axilla, however there is still a need for a banana-shaped bag to provide for elbow flexion.

Twenty below-knee amputations were managed with CET between March 1974 and December 1975. The result of that clinical study is incorporated in the first part of this paper.

Since December 1975, 20 additional below-knee amputations have been treated with the equipment in Seattle. Use of the device during the past 12 months has also included treatment of upper and lower limb edema states (5 cases) in which amputation was not involved. Application of CET concepts has been extended in modified form, with the development of the MACE at Prosthetics Research Study, for control of limb edema conditions and for the immediate management of closed limb trauma, primarily about the knee and ankle.

At the present time, four CET units are available to this investigator. Two are stationed at the Seattle VA Hospital, principally for the postsurgical care of lower-limb amputations, and a third is located at Providence Hospital in Seattle for similar use. A fourth unit is situated at the Harborview Medical Center, Seattle (a University of Washington affiliate) where a wide variety of fresh trauma, including compartmental syndromes, closed fractures, and joint injuries, are available for study.

The simplified MACE unit has been loaned directly to the Department of Biomedical Engineering and Orthopaedics at the University of Washington, where basic research is underway to study the effects of external pressure. Here, the device is being used (in conjunction with supplementary electronic equipment) to measure surface and muscle blood flow in the limbs of a rabbit animal model. Data derived from these studies will be translated to clinical

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application of the CET and related management systems.

### **Conclusions Reported from Investigating Centers**

#### *Advantages of CET:*

1. CET is easy to apply and to operate.
2. CET provides uniform pressure, regardless of limb volume changes, there is no danger of a tourniquet effect or localized pressure areas.
3. CET provides a dry wound surface and sterile environment, conducive to wound healing.
4. CET allows visual inspection and palpation of the wound site without disturbing the sterile environment.
5. CET provides edema control.
6. In the absence of postsurgical complications, patients report minimal discomfort using CET.
7. Patient acceptance of CET is positive.
8. CET permits freedom to carry out knee flexion exercises.

#### *Disadvantages of CET:*

1. Originally the noise disturbed patients. This problem is now essentially eliminated with the quieter Mk II CET.
2. Weightbearing is delayed with CET.
3. Mobility is somewhat limited with CET; some patients become restless if treatment is extended for a long period of time.
4. Careful nursing is required to prevent decubiti in debilitated patients.
5. CET does not provide residual limb contouring.
6. Syme's amputees have difficulty ambulating because the dressing bag hose connection contacts the floor. (Redesigned treatment bags have helped to alleviate this problem.)

### **Summary of CET Equipment Malfunctions**

Mechanical problems encountered during use of the equipment were corrected through a joint effort on the part of the PRS engineering staff, BRADU, and appropriate personnel at the various trial centers. The most common equipment malfunction was cooling fan failure, which occurred at the Duke University Medical Center, the Castle Point VA Hospital, and in three of the four units at the Prosthetics Research Study. In addition, it was necessary to rewind the main compressor motor at Castle Point and to replace a burned-out main blower bearing at the San Francisco VA Hospital. Current Mk II CET units employ an improved cooling fan model, which provides increased durability.

#### Recommendations from Investigating Centers

Overall experience with CET at the participating trial centers has been positive. All investigators view this system of management as a viable technique and are enthusiastic about its continued use and extension into other areas of treatment. The following recommendations were suggested at an evaluation workshop held in Seattle in May 1976:

1. At this time, CET offers an alternative to conventional systems of wound management. A long-range controlled and randomized study is needed to ascertain the effectiveness of CET on wound healing progress, i.e., to determine where CET stands in relation to conventional techniques for managing ischemic ulcers, amputations, and hand pathology.
2. There is a need to extend the use of CET into several areas of treatment in order to define where CET can be most effectively used.
3. A jointly controlled study involving all investigating centers, will provide comparative results in a short period of time.
4. Further basic research should be carried out to determine the effects of CET on tissue physiology. Particular emphasis should be placed upon the nature of the CET cycle times and pressure phases as they relate to the status of peripheral circulation, tissue compartment pressure changes, and tissue gas concentrations.
5. Immobilization of the limb within the treatment bag is an important area to explore, e.g., the possibility of splints to support fractures or the long posterior flap in below-knee amputation surgery.
6. Protocols should be prepared for the above phases of CET investigation.

#### DISCUSSION AND CONCLUSIONS

Wound healing, a process of tissue regeneration and repair, relates directly to restoration of function. The external physical environment in which tissues heal and the influence of these environmental forces on clinical wound healing are the bases of this study.

Thermal injury, i.e., burn and frostbite, has attracted the most interest in external healing environment. There is need for improvement in understanding and treating all types of tissue trauma in an optimum physical environment during healing.

This study outlines our observations using a controlled system of environmental management following the surgery of amputation. Amputations were selected as a pilot clinical study because



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this operation without distal tissue to support constitutes an excellent, controllable wound healing model. Our experience in the first 20 below-knee amputations using this specific Controlled Environment Treatment technique has encouraged us to extend this management system to a wide variety of types of trauma and disease of the limbs. Contraindications to this management system would be those circumstances in which the application of external pressures could be harmful. Posttraumatic compartmental syndromes unrelieved by fasciotomy, infections (particularly closed space infections), undrained hematomas, and thromboembolic states exemplify situations in which CET could possibly produce harm.

A major drawback of the CET device in the management of amputees is the inability to ambulate these patients, except with difficulty and with no terminal wound support. We are strongly committed to postsurgical immobilization, i.e., a rigid dressing. It is of considerable advantage to be able to visually inspect the healing amputation with CET, but we favor a rigid dressing for support. With these factors in mind, we are currently exploring methods to immobilize the residual limb within the treatment bag in order to obtain the advantages of external wound support and tissue rest, as well as the modalities provided by the CET equipment.

Good experience using this specific system of Controlled Environment Treatment has encouraged the cooperating centers not only to continue it for amputations but to extend this management technique to a wide variety of trauma and disease of the limbs.

Prosthetics Research Study anticipates extended use of the CET. We believe it fills a need in many areas of limb and, in fact, trunk trauma disease. We continue to document case results and plan to record our experience with further publication.

#### **ACKNOWLEDGMENT**

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**A STUDY OF INTERFACE PRESSURES IN THE  
BELOW-KNEE PROSTHESIS  
(PHYSIOLOGICAL SUSPENSION: AN INTERIM REPORT<sup>a</sup>)**

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**INTRODUCTION**

Since its inception, the Prosthetics Research Study has attempted to maximize retention and stabilization of residual limb musculature in the below-knee amputation. Combined with myoplastic technique, Immediate Postoperative Prosthetic fitting, training of residual limb muscles, and an appropriate definitive prosthesis, an effective, functional end organ is achieved.

Clinical observation has shown that certain below-knee amputees are able to utilize their prostheses without built-in suspension (such as the PTS) or auxiliary suspension. It was hypothesized that strength and muscle development in the residual limb would facilitate prosthetic suspension.

The present report provides a detailed investigation of certain parameters of muscle activity and pressure relationships within prosthetic sockets; a preliminary report has been previously published (1). A

<sup>a</sup>This work was performed under Veterans Administration Contract No. V663P-784.

study of five below-knee amputees, undertaken to determine socket interface pressures and the feasibility of "physiological suspension," is reported here.

## **METHODS AND MATERIALS**

### **Patient Selection**

The following criteria were established for patient selection:

1. The study was limited to unilateral below-knee amputees who had undergone amputation because of trauma.
2. The surgical technique was myoplastic with long posterior skin flap and an anterior suture line.
3. Postsurgical management was either Immediate Postoperative Prosthetic fitting (IPOP) or Controlled Environment Treatment (followed by some elements of IPOP).
4. The length of the residual limb was 6 to 8 in, which was considered adequate for sufficient gastrocnemius length below the bifurcation of the gastrocnemius heads.
5. Patients were at least 6 months postamputation and they were using their definitive prostheses effectively.

### **Patient Evaluation**

Initially, the patients were interviewed individually, at which time the study parameters were explained. A clinical subjective evaluation by a prosthetist, an engineer and a physical therapist was performed. Physical examinations of the residual limb included:

1. Visual inspection and palpation of residual limb for tender areas and for degree of muscle activity.
2. Evaluation of type, condition, and fit of present prosthesis.
3. Analysis of gait with present prosthesis.
4. Routine X-rays of prosthetic fit.(2)

### **Photogrammetry**

It was assumed and subsequently shown that peak muscle motion or rise would indicate the point of highest pressure at the residual limb socket interface when the muscles were contracted. In order to locate such areas of highest pressure, each patient underwent a photogrammetric study of his residual limb(3). Photogrammetry is a three-dimensional photographic technique commonly used for making contour maps of land. The patient was photographed standing without his prosthesis. Anterior, lateral, and posterior views of his residual limb were taken, in both relaxed and contracted muscle positions.

Resulting photographs, processed into direct contour maps through a Balplex plotter, were enlarged to full scale and transferred to clear acetate sheets. These transparencies were used as overlays to compare the residual limb contour in relaxed and contracted positions, illustrating physical surface changes which occurred on the residual limb (Fig. 1). The overlays assured correct and repeatable positioning of pressure transducers in the areas of gross muscular changes; i.e., posterior gastrocnemius bulge.

#### Prostheses

To ensure similarity in the prosthetic technique used, the same prosthetist fabricated and fitted all prosthetic appliances. The type of suspension used in the patient's previous prosthesis was incorporated into a new prosthesis for each patient.

Four patients had PTB sockets with soft liners: of these, two used cuff suspension (Patients No. 1 and No. 2) and two had no auxiliary suspension (Patients No. 3 and No. 4). Patient No. 5 had a PTS socket with a soft liner and a built-in wedge. Each patient wore his new prosthesis (weight approximately 4 lb including the shoe) for not less than 1 week before further testing was done.

Additional instrumentation was used on one patient's prosthesis (No. 4) to determine the amount of displacement which occurred

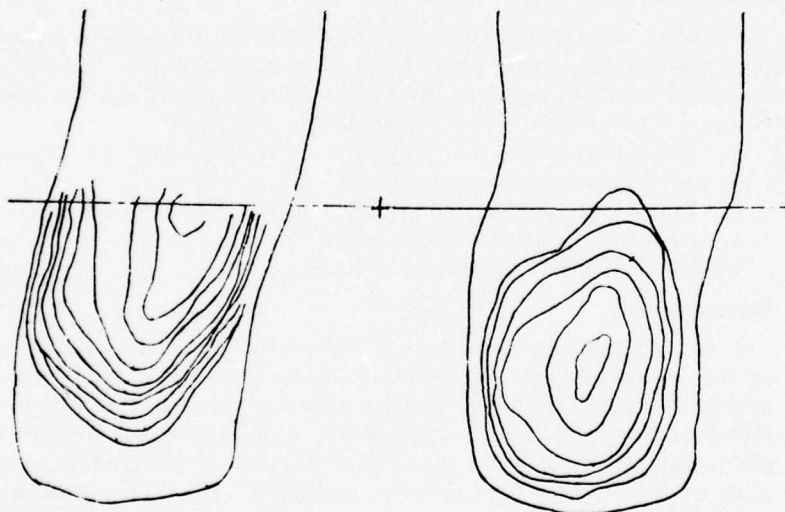
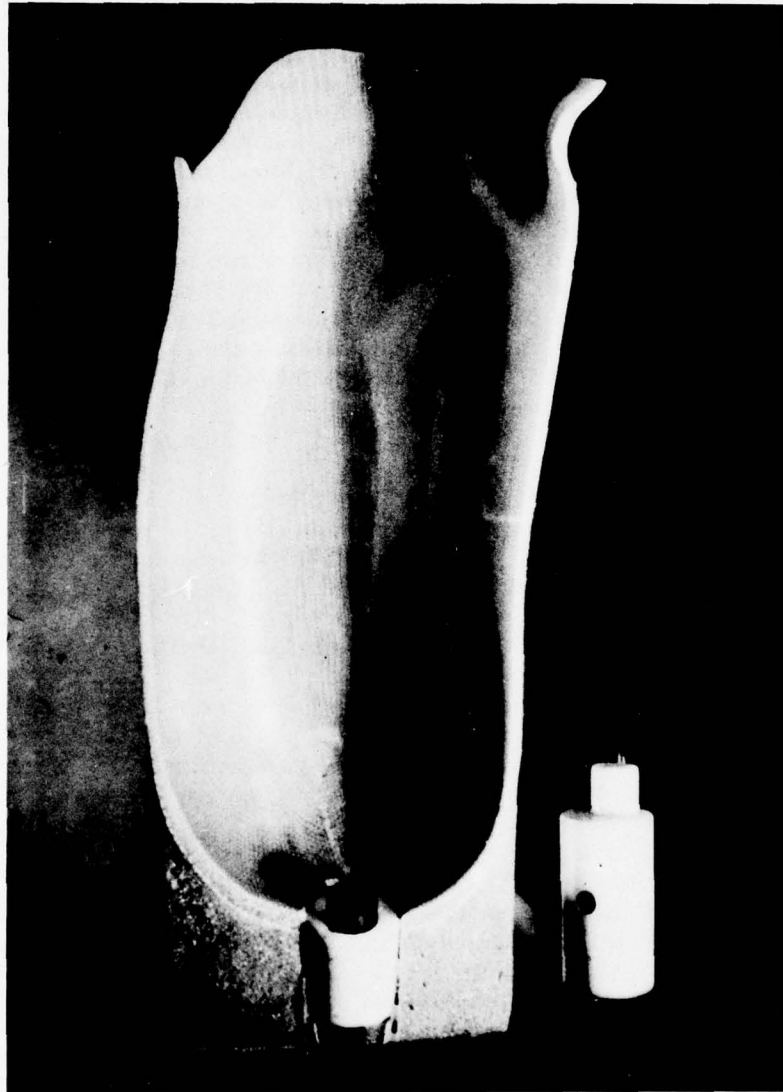


FIGURE 1. — Contour lines such as these are transferred full-scale to transparent acetate sheets. The contour lines here illustrate physical surface differences between a residual limb in a relaxed state (at left) and contracted (at right). Posterior views.



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between the distal portion of the residual limb and the bottom of the socket while walking. A displacement sensor was designed to give continuous readout of the resulting separation (Fig. 2).



**FIGURE 2.**—Sensor designed to determine amount of displacement which occurred between distal portion of the residual limb and the bottom of the socket while walking.

The device consists of two Teflon cylinders arranged one inside the other. The outer cylinder is 1 in. in diameter and 2 in. long; the inner one  $\frac{1}{2}$  in. in diameter and  $1\frac{3}{4}$  in. long. The lower half of the inner cylinder is wrapped with resistance wire. The outer cylinder has a small, spring-loaded ball bearing which makes contact with the resistance wire, forming a potentiometer.

A spring ensures that, without load, the inner cylinder extends  $\frac{3}{4}$  in beyond the outer one. As the limb is inserted into the socket, the inner cylinder is retracted into the outer, changing the electrical resistance of the device. In this way, a correlation between the resistance and the cylinder extended height can be made; this also relates to the distal separation between the residual limb and the bottom of the socket.

The sensor was recessed into the bottom of two sockets (one hard socket and one socket filled with a soft liner). There was no difference in the amount of displacement seen, regardless of whether the patient wore a hard or soft socket. Because the patient felt most comfortable in the soft liner, test prostheses for all patients were made with this feature.

#### **Interface Pressure Evaluation**

Six thin pressure transducers (Kulite LQ-125), which were zeroed at atmospheric pressure, were affixed directly to the patient's skin with Micropore (3M) tape. Placement of the transducers (Fig. 3) along the posterior portion of the patient's residual limb was along a vertical line as follows:

One placed at the center of peak muscle activity (as determined by the photogrammetric overlays);

Two 2 cm and 4 cm proximal from the center; two 2 cm and 4 cm distal from the center; and one at the most distal portion of the residual limb (Fig. 4). To ensure accurate placement of the sensors for repeated study, the transducer placement was then charted on the patient's photogrammetric overlays.

#### **Muscle Activity**

Surface EMG electrodes were also taped over the gastrocnemius and tibialis anterior muscles of both lower limbs. Placement was selected to record maximum muscle activity (4) of both the residual limb and the "normal" limb of all patients, as it occurred during specific phases of gait cycle. No attempt was made to correlate the amount of muscle firing by each patient with other patients or test runs. Of greater interest was to determine when the residual limb musculature fired during the gait cycle.

Burgess and Moore: Interface Pressures in Below-Knee Prosthesis

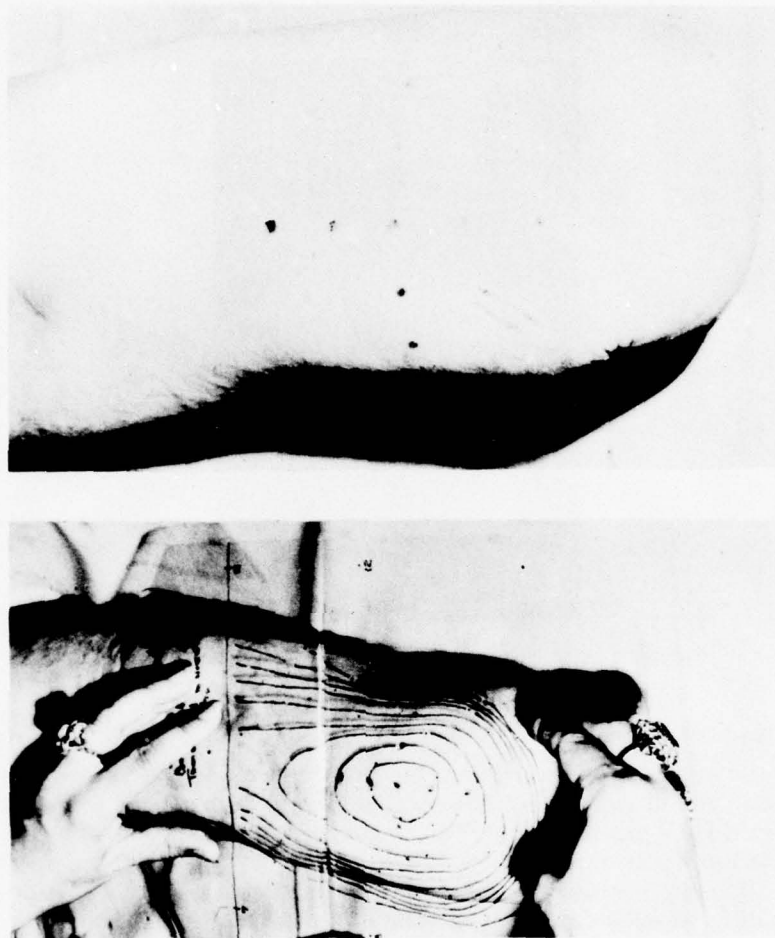


FIGURE 3.—Acetate overlay placed on patient's residual limb: "dots" chart placement of pressure transducers.

In order to correlate the cycles of the residual and contralateral limbs' muscle activity, foot switches were taped under the heel, and 2 in from the tip, of each shoe. This switching information was translated into a Visicorder grapher by Medtronic, Inc., signal conditioner, and represented the following phases of gait: heel strike (HS), foot flat (FF), heel rise (HR), and toe off (TO).



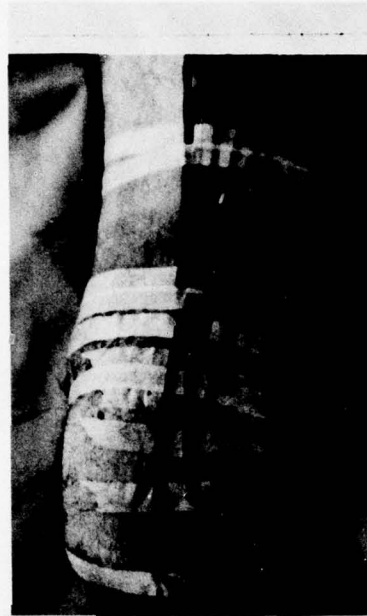


FIGURE 4.—Transducer placement in a vertical line on the residual limb.

#### Dynamic Evaluation

After all electrodes and transducers were secured, a nylon stocking was carefully pulled over the residual limb to keep all lead wires flat against the patient's skin. The patient then donned his prosthesis in the routine manner (Fig. 5).

All wire leads were connected to a small control box which the patient wore on a waist belt. The information was fed through an "umbilical cord" to a 13 channel Honeywell 1912 Visicorder. Four EMG channels, six pressure channels, and two foot switch channels were used. The thirteenth channel was used for the displacement sensor.

All patients were then instructed to walk along a 60 ft walkway. Each patient traversed the course eight times using his normal mode of suspension. With the two patients who used cuff suspension, ambulation was then repeated without auxiliary suspension.

The patients were observed to build up speed at the beginning and decrease near the end of the walkway: therefore, for graphing purposes, one gait cycle was selected at random from the middle of each

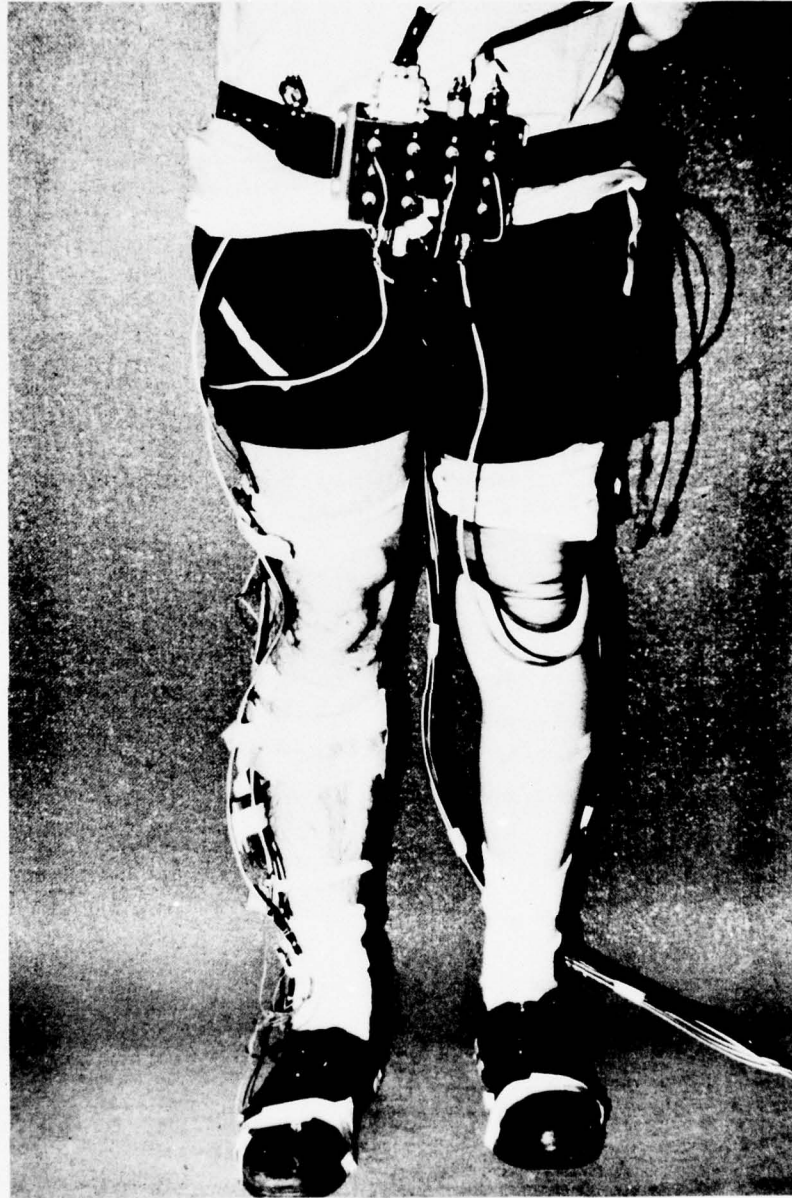


FIGURE 5.—Patient with EMG, pressure transducers, and foot switch leads in place: he is now ready for dynamic evaluation.

of the eight runs, and averaged, to produce the graphs used for evaluation.

#### Observations

The pressures recorded for each patient's residual limb during the swing phase showed the same pattern (Fig. 6). This similarity held true when the two patients with cuff suspension ambulated without their cuffs.

Studies conducted by Appoldt, et al. (5) have indicated that pressure gages which are not flush with the socket wall will give inaccurate readings at higher pressure, while at the lower pressures, readings are more likely to be correct. Since this study concentrated on swing phase pressures, which are reasonably low, pressure readings were considered accurate.

An interesting observation was made when testing distal displacement. The generally accepted premise is that more than  $\frac{1}{4}$  in of pistoning in swing phase is an indication of a poorly fitting prosthesis. However, the tests with a distal displacement sensor on one patient

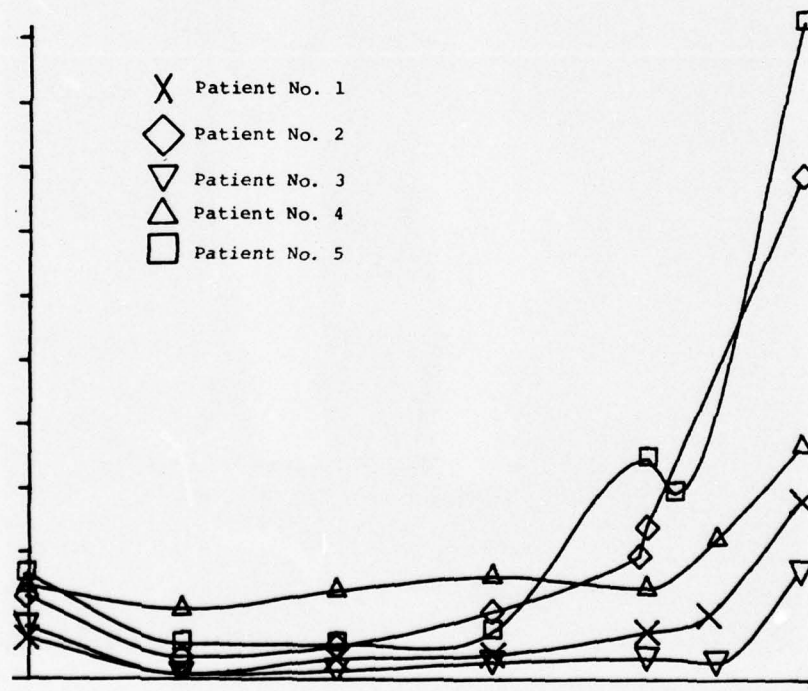


FIGURE 6.—Average pressures recorded of five patients at transducer (4+ cm).



(No. 4) revealed  $\frac{3}{4}$  in of pistoning, without disturbing the patient's comfort or gait pattern. This surprising result was confirmed by Grevsten, et al.(6), in their study of skeletal displacement, and by our own X-ray examination (Fig. 7). In all five patients, X-rays of their residual limbs within prostheses in simulated swing phase confirmed a displacement of more than  $\frac{1}{4}$  in.

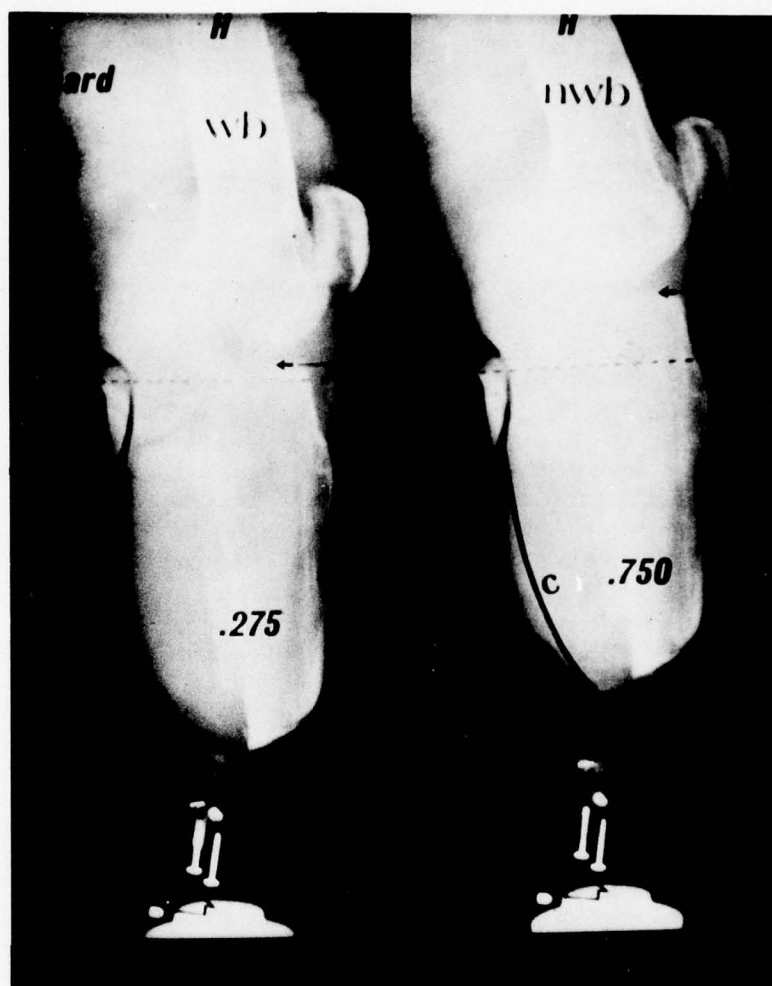


FIGURE 7.—X-rays of patient No. 4: at left, weight-bearing and at right, non-weight-bearing, revealing displacement in contracted position.

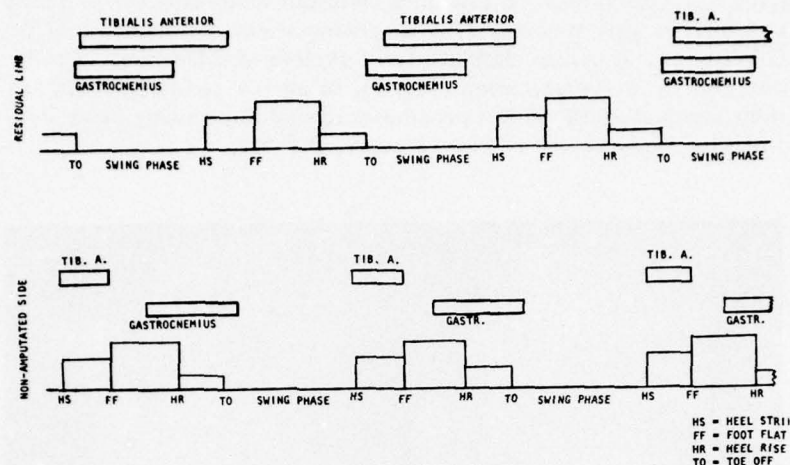


FIGURE 8.—Representation of muscle firing overlap in swing on the residual and normal limbs.

EMG studies were done to determine when muscle activity in the gastrocnemius and tibialis anterior muscles occurred. On the non-amputated side, the gastrocnemius fired mid-foot-flat through toe off, and the tibialis anterior fired at heel strike. In the residual limb, the gastrocnemius fired from toe off through mid swing, and the tibialis anterior from swing to mid-heel-strike on that side. It was noted that neither muscle fired during swing on the non-amputated side, while both overlapped in swing on the residual limb (Fig. 8).

Patients No. 1 and No. 2, who normally used cuff suspension, demonstrated no graphic difference between their pressure and gait parameters as they walked with and without their suspension for normal ambulation. (This study did not evaluate any other activities of daily living, e.g., up and down stairs and ramps, and rising from sitting to standing.)

While their pressures, EMG, and gait patterns were similar, patient No. 2 showed a considerable gastrocnemius contour bulge with the photogrammetric pictures, but patient No. 1 did not. In fact, No. 1 did not show any demonstrable differences in either the relaxed or contracted positions. For the above reason, patient No. 1's pressure transducers were set up on a purely symmetrical basis, corresponding to the positions on the other four patients.

Of the two patients not using auxiliary suspension, patient No. 4 appeared to suspend his limb by muscle contractions alone. With the patient sitting down, and with his residual limb straight or bent (45 deg) and muscles relaxed, a very small amount of force (less than

**Burgess and Moore: Interface Pressures in Below-Knee Prosthesis**

10 lb) removed his prosthesis. However, with his muscles contracted, it was impossible to remove his prosthesis without exerting a force greater than 45 lb.

Patient No. 3 was also able to ambulate without auxiliary suspension. In his case, however, whether residual limb muscles were contracted or relaxed, it was still difficult to remove the prosthesis. X-rays showed a bony callus at the proximal end of the fibula (Fig. 9)

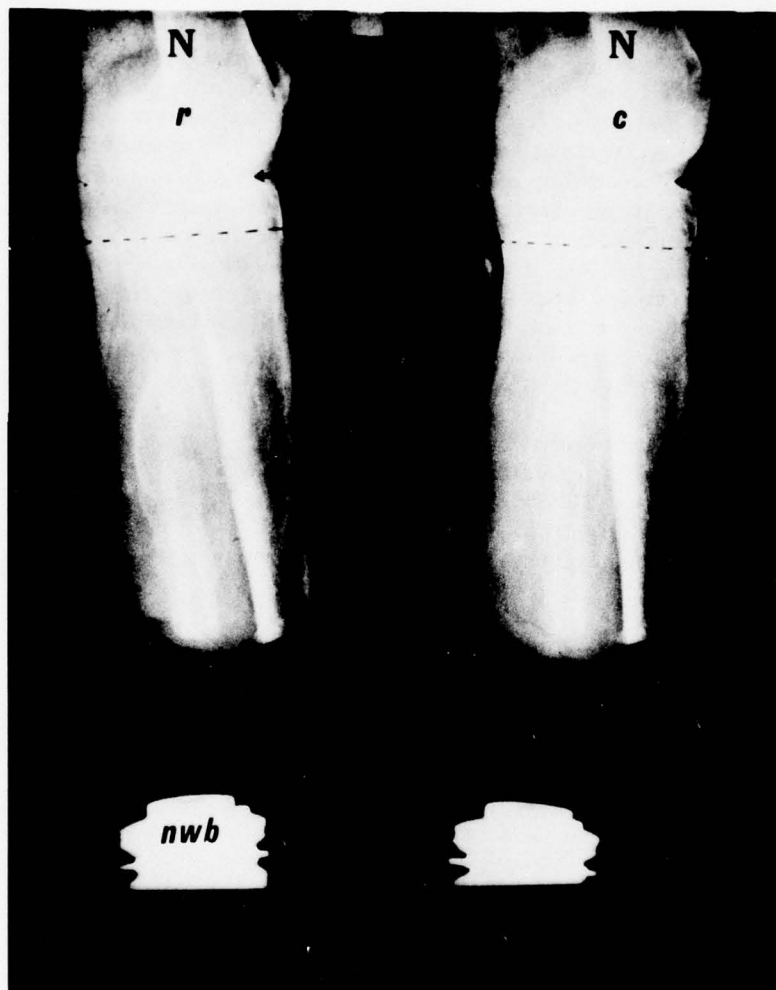


FIGURE 9.—X-ray of patient No. 3's residual limb, showing bony callus at proximal end of fibula.



which gave the patient minor prosthetic donning problems; however, once the limb was in, it was difficult to remove the prosthesis.

#### Conclusions

At this interim point, we have accumulated data on the interface pressures of what we consider the key areas for physiological suspension, these being areas of peak muscle motion of the gastrocnemius as shown by photogrammetry. In conjunction with these data we have determined "normal" EMG firing patterns for both lower limbs during the gait cycle, as indicated by the foot switches.

All this information has indicated that there is no basic difference between patients ambulating on a straight level walkway with or without auxiliary suspension. With this in mind, future studies would entail the fabrication of sockets for the three patients still using some type of auxiliary suspension. Their new sockets would not incorporate any type of suspension. Socket modifications could be made along the line of Blevens (7) to enhance physiological suspension capabilities. They would then be trained in the active use of their residual limb muscles through physical therapy and biofeedback training. The tests conducted in this interim report would be repeated at monthly intervals to determine the patient's progress with their new limbs.

As another consideration, surgical procedures for new below-knee amputees could be modified to augment the ability of the patient's residual limb to adhere to the socket. On those patients who do not use auxiliary suspension, studies could be made to determine if they have any problems keeping their prosthesis on during other activities of daily living.

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## **SLIPPING CANE AND CRUTCH TIPS**

### **PART I—STATIC PERFORMANCE OF CURRENT DEVICES**

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#### **INTRODUCTION**

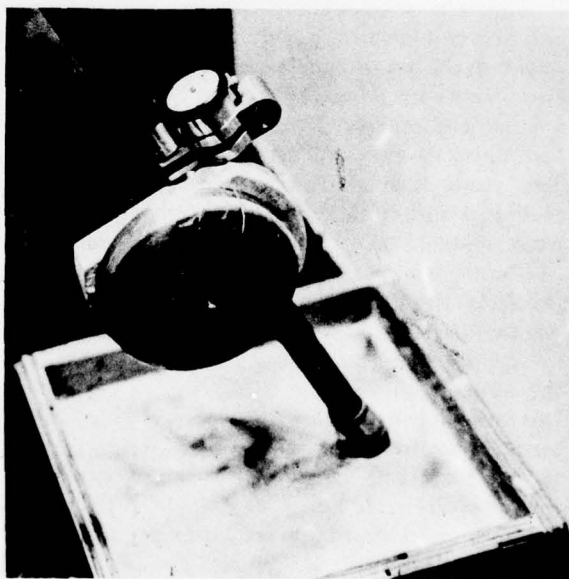
Undesired slipping or sliding of cane and crutch tips can lead to further injuries of those already handicapped. The problem is well known, yet the literature reflects relatively little sustained effort to improve slip characteristics. Kennaway (1) has suggested that skid-resistance depends upon hysteresis, which depends upon the material and the temperature, but that empirical trials are necessary. Practical notes on the art of cane-assisted gait have been given by Murphy (2). Cane forces have been examined by Murray, et al. (3,4).

This preliminary paper reports a reconnaissance of the slip performances of cane and crutch tips currently available to the disabled. This study is properly regarded as a point of entry into a difficult technical and clinical area. It is only by knowing currently available performance characteristics that we may seek means of improvement.

The conditions necessitating improvement in performance are precisely those that are poorly understood from the viewpoint of engineering mechanics. Thus, slippages on ice and on wet soapy tiles involve mechanisms that are neither of the dry-friction type nor of the hydrodynamic lubrication type, both of which are well defined. Instead, the domain of interest is that vague intermediate area termed "boundary lubrication" wherein the chemistry of the contacting surfaces is significant to the frictional process, in addition to the usual physical factors. Despite intensive effort by the automobile industry over many generations, the slip of rubber tires, studded tires, and chains on ice remains largely a matter of empirical testing



FIGURE 1.—Instrumented cane in use (soapy tile test). Operator plants cane vertically, increases load to a desired value and then slowly rotates cane about the tip until slip occurs.





and of compromises (5). It is, therefore, not surprising that the cane and crutch tip problem lacks an ideal solution.

As our concern is with the unresolved or potentially unsatisfactory aspects of contemporary devices, we have deliberately chosen two situations in which clinically there seems major risk of slip, in which to measure performances. There are slip measurements on (i) ice and on (ii) soapy wet tile of two types of surface roughness. What follows are cane and crutch tip performance results on these surfaces under slowly varying quasi-static conditions. Obviously, dynamic loads and many practical aspects must later be considered in selecting clinically useful solutions.

#### EXPERIMENTAL METHODS AND PROCEDURE

The basic measurement tool for the present preliminary experiments is a cane equipped with instrumentation (Fig. 1 and 2) indicating both the axial compressive load (termed "Thrust") and the angular attitude with respect to the vertical. A typical wooden

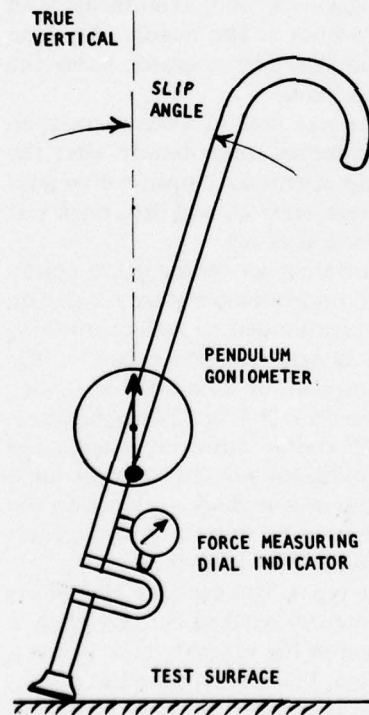


FIGURE 2.—Instrumented cane schematic. The pendulum goniometer reads the angle of inclination of the cane with respect to the vertical. The dial indicator is calibrated to reflect axial thrust loads.

orthopedic cane of approximately 1.0 in. (25 mm) diameter was used. Axial load is determined by measuring, with the aid of a dial indicator, the deflection of a small U-shaped member on the cane axis. (Adequate calibration is achieved by pressing the complete cane device against a bathroom scale.) Angular position from the vertical is determined by an indicator attached to a pendulum bob; in effect, a continuously-reading goniometer results. Both instruments have little friction or hysteresis; however, dynamic response is obviously of low quality. The pendulum is undamped and must be handled carefully to avoid acceleration errors. In each case the readout depends on the vision of the experimenter, with inevitable reaction-time and reading errors. Still, it is estimated that under the slowly moving dynamic tests employed in this work, axial load is maintained within  $\pm 15$  percent of the loads reported. Similarly it is estimated that angles reported are correct to within  $\pm 3$  deg.

In use, the instrumented cane is equipped with the tip selected for test and then slowly pressed against a test surface in a perpendicular attitude. When a desired loading is achieved, the cane is slowly rotated about the tip, maintaining a constant axial test load through operator feedback. The operator endeavors to provide only axial-thrust load and to minimize bending loads or torques at the handle. At some angle from the vertical, the cane will slip. The operator notes the angle at which slip occurs, and the test load.

The icy surface used in all ice tests was that of a commercial indoor ice skating rink. Tests were conducted immediately after the daily shaving, flooding, and refreezing operation employed to level the rink surface. The ice appeared clear, smooth and dry. Each test was conducted on a separate, fresh portion of ice.

Ice tests were conducted under differing air temperature conditions. Although the rink was enclosed, no air temperature regulation was available. Thus the air temperature tended to reflect outdoor ambient temperature. Two basic test air temperatures existed in the course of these tests; a low temperature in the 20's F ( $-7$  to  $-1$  deg Celsius) and a high temperature in the 40's F ( $+4$  to  $+10$  deg Celsius). The ice appeared solid and dry at all times. However, it appeared that the variable air temperature condition, possibly permitting a film of moisture at the higher air temperature, had an effect on the data. The following results carry temperature notations in the form of either an H (high temperature) or an L (low temperature).

Tested soapy tiles were of two basic types. One (quarry tile) offers a relatively rough surface and is frequently used in current kitchen and fast food restaurant design. The other tile is highly glazed and is similar to that seen in older bathrooms. The results note the tiles as "rough" and "smooth." In use, the tiles were flooded (covered)

with a mixture of liquid hand soap and water.

Raw data resulting from tests of a typical cane tip are given in Figure 3. All test points are plotted, permitting an assessment of scatter. In each case, three data points were obtained at a given test parameter. The letter L superimposed on the ice results means that the data were gathered at a low test temperature as described above. All subsequent results are presented without data points, in the style of Figure 4, so as to gain clarity. The reader may be assured that the scatter throughout the test series is typified by the results as shown in Figure 3.

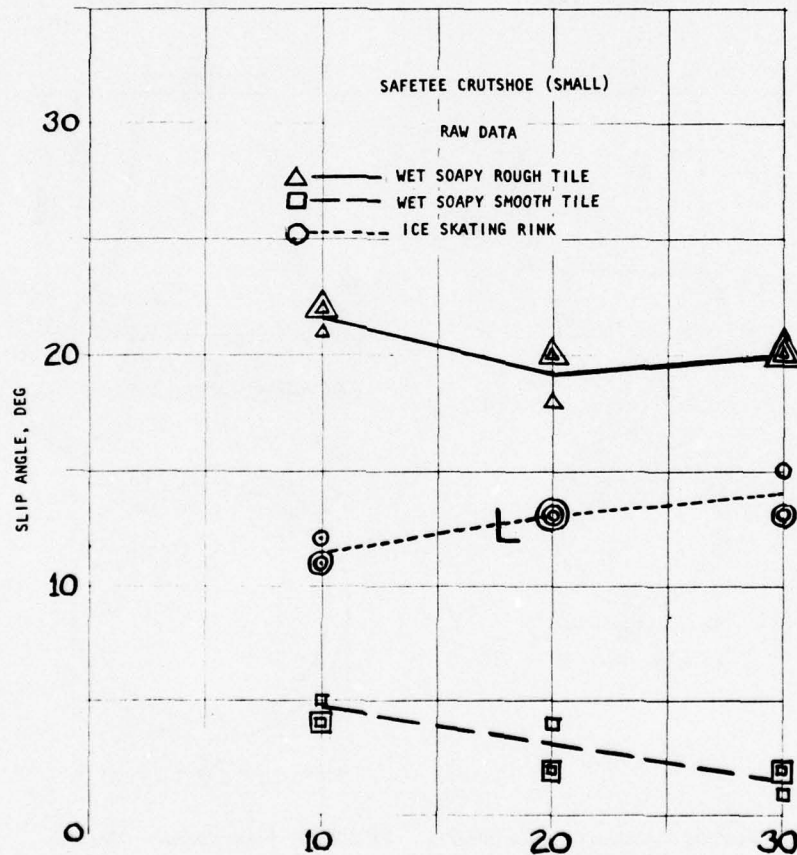


FIGURE 3.—Slip angle vs. cane-thrust on various test surfaces. This graph shows typical raw data: all data points have been plotted here to illustrate the scatter encountered in this work. Subsequent figures show only average values.



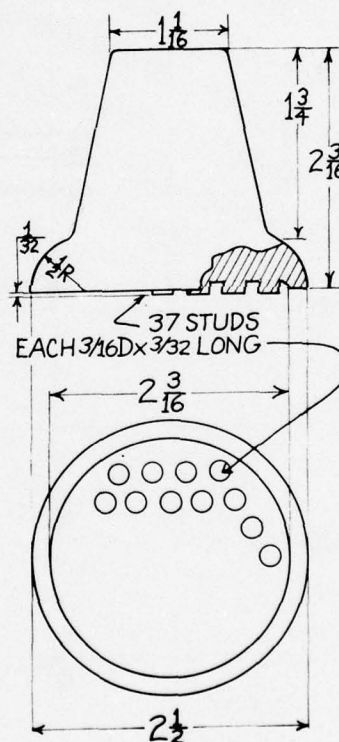
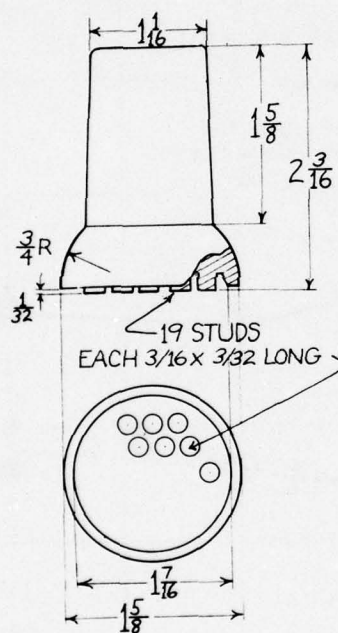
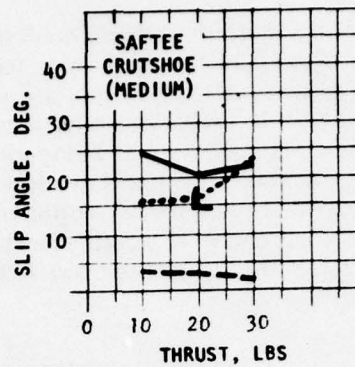
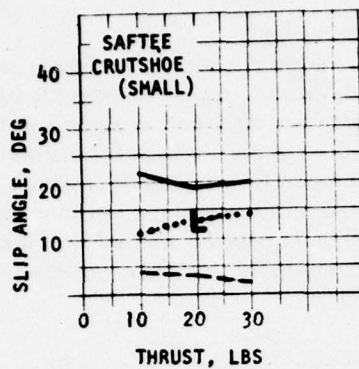


FIGURE 4.—Saftee Crutshoe (Small).

FIGURE 5.—Saftee Crutshoe (Medium).

FIGURES 4-17.—Slip angle vs. cane-thrust on various test surfaces. Lower figure portion shows the device tested.

Bennett and Murphy: Slipping Cane and Crutch Tips

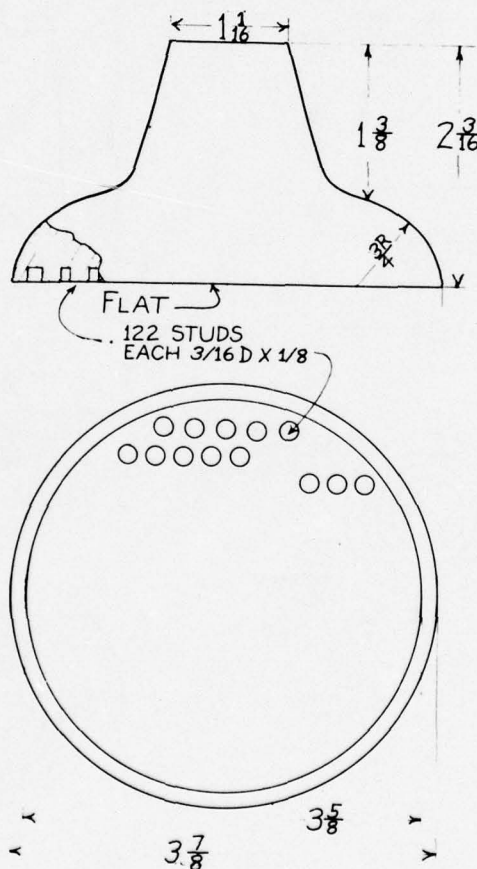
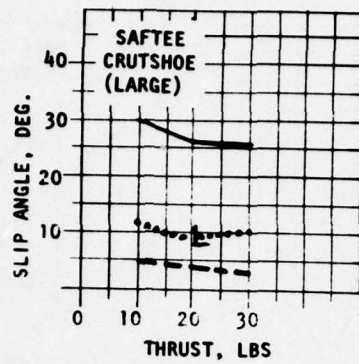


FIGURE 6.—Saffee Crutshoe (Large).

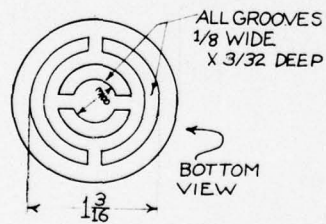
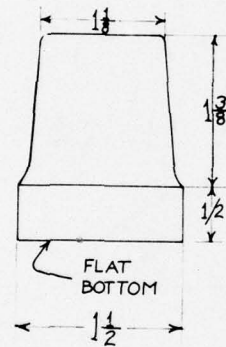
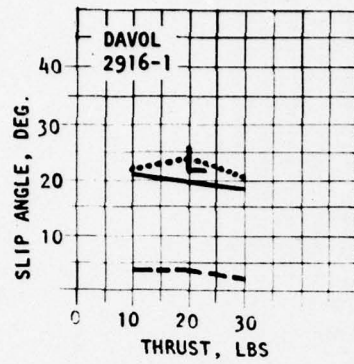


FIGURE 7.—Davol 2916-1

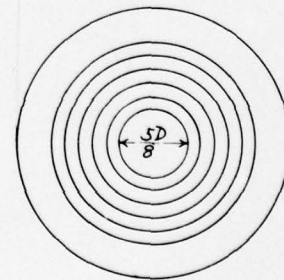
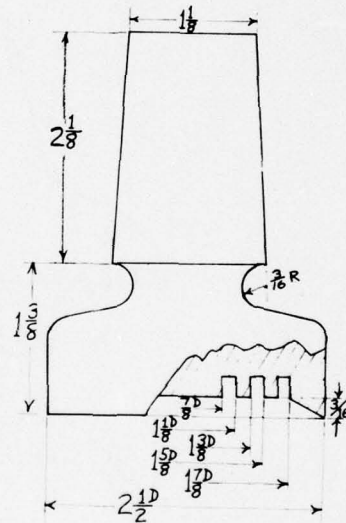
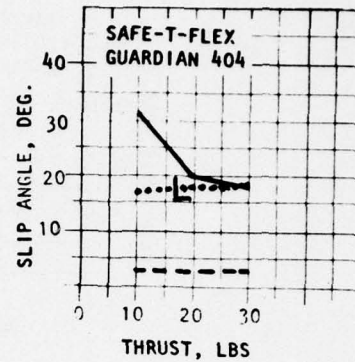


FIGURE 8.—Safe T Flex Guardian 404



Bennett and Murphy: Slipping Cane and Crutch Tips

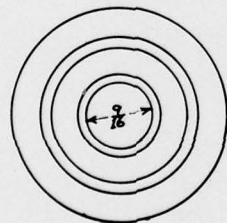
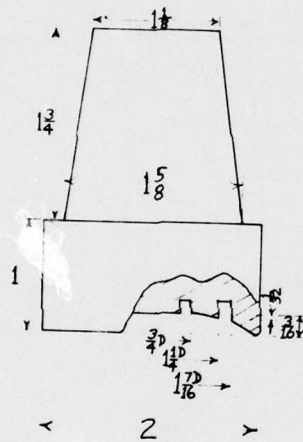
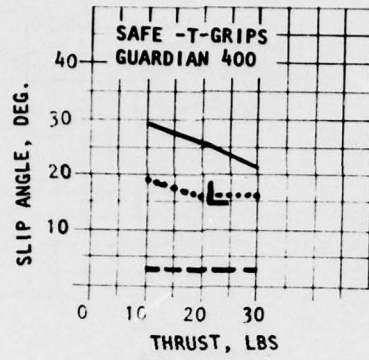


FIGURE 9.—Safe-T-Grips Guardian 400

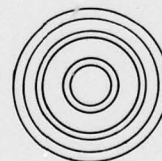
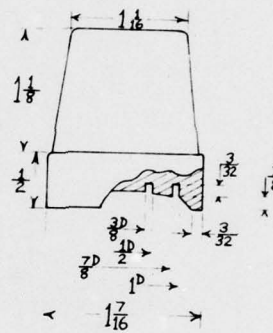
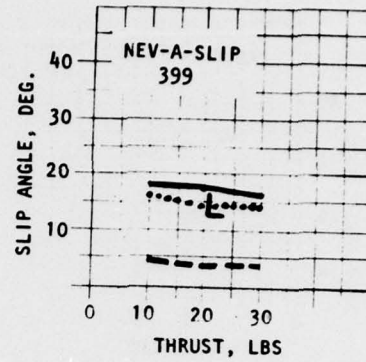
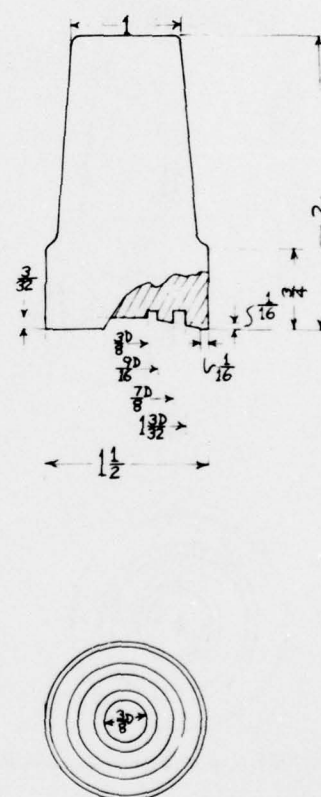
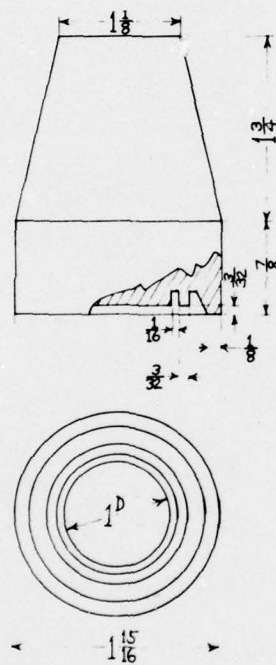
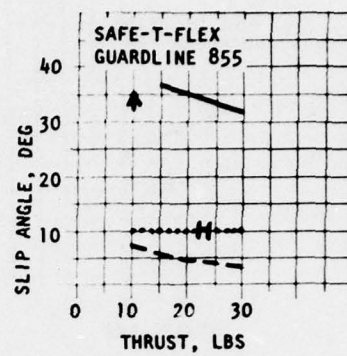
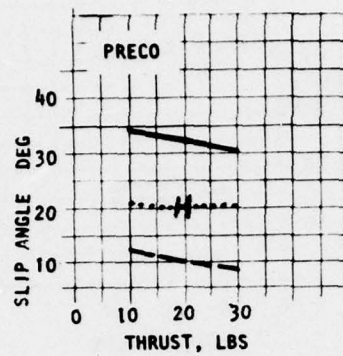


FIGURE 10.—Nev-A-Slip 399.



**FIGURE 11.—PRECO (Precision Grinding and Manufacturing Co.)**

**FIGURE 12.—Safe T Flex Guardline 855.**

Bennett and Murphy: Slipping Cane and Crutch Tips

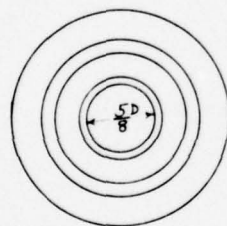
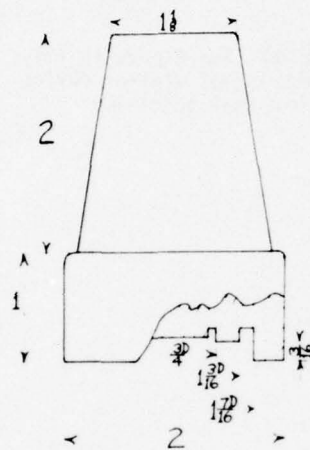
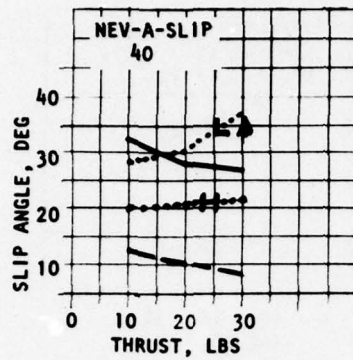


FIGURE 13.—Nev-A-Slip 40

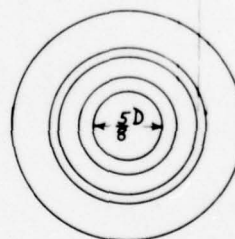
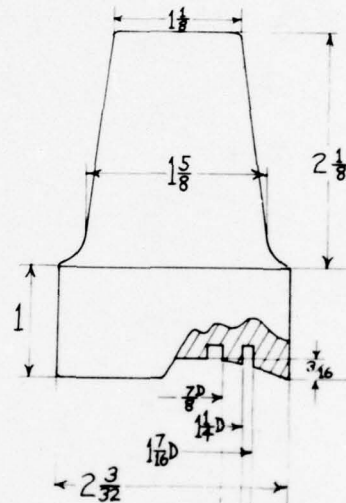
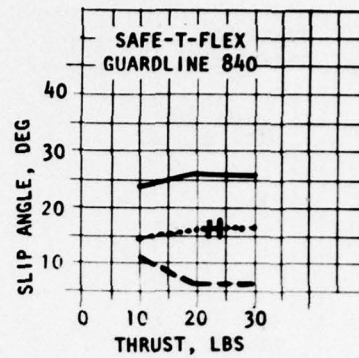
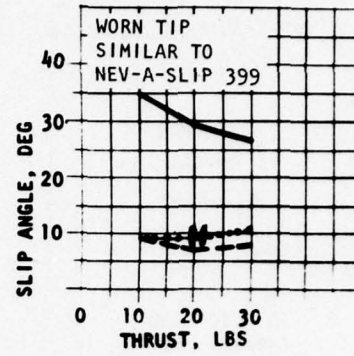
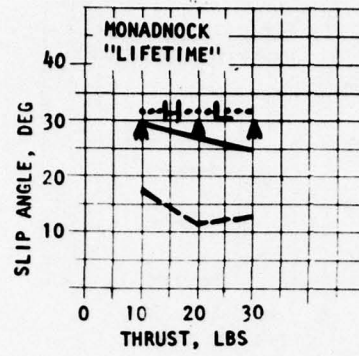
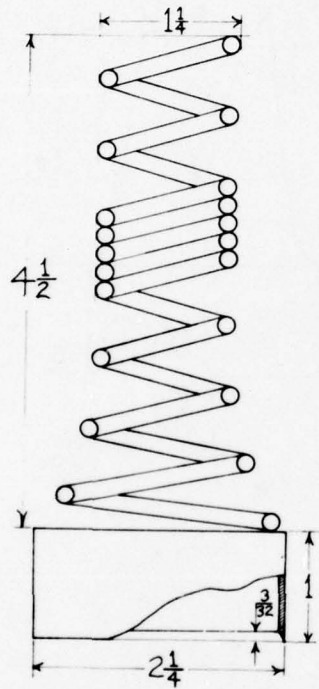


FIGURE 14.—Safe T Flex Guardline 840.





NOTE: See Figure 10 for drawing of similar device in normal condition.

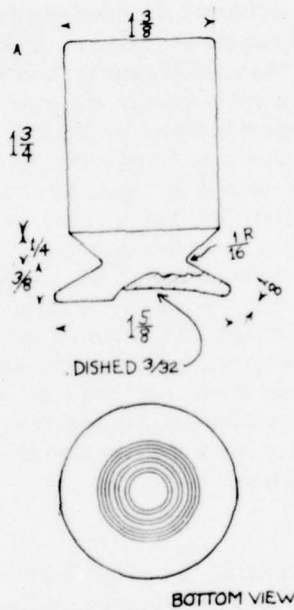
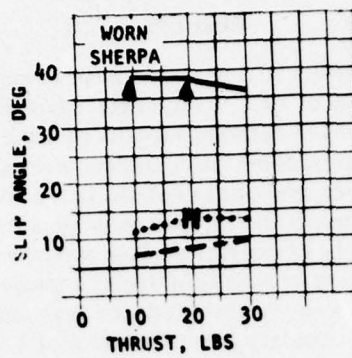


SIDE VIEW

FIGURE 15.—Monadnock "Lifetime."

FIGURE 16.—Worn Tip.

Bennett and Murphy: Slipping Cane and Crutch Tips



4 ANNULAR RINGS  
ON 3/8, 1/4, 9/16, AND 3/8 CENTERS  
EACH 1/32 WIDE X 1/32 DEEP

FIGURE 17.—Worn Sherpa.

## RESULTS

In assessing slip results it is useful to have a tentative standard of acceptable performance; i.e., what angle of inclination from the vertical is actually used in deriving support by cane users? Such data (the working angle) must come from clinical tests and is not pursued here in depth. However, one of us does use a set of canes on an everyday basis. Observations of this subject indicate a maximum working angle of approximately 17 deg on a surface perceived as "safe." While the dangers of drawing conclusions from a single test subject are obvious, nonetheless some useful guidance may result from the following rule-of-thumb. Applying a safety factor of 1.5 to the measured working angle of 17 deg, we have a desired working angle of approximately 25 deg. Rule-of-thumb: *Any slip angle well below 25 deg can be dangerous; any slip angle well above 25 deg is likely to be safe.* The gross nature of the rule-of-thumb should be emphasized; it is useful only as a rough guide in selecting from an infinite number of situations a few test cases likely to be clinically significant.

A larger angle between cane shaft and vertical just before slippage occurs (slip angle) is viewed as clinically desirable, permitting the patient to take longer strides and to move more rapidly and confidently. Also, a larger angle implies that the patient can be more confident on sloping terrain, whether local driveways and ramps or major hills. The user may be intuitively estimating risks, shortening his stride and slowing down as he perceives greater danger.

The slip angle is analogous to the friction angle concept employed in engineering practice. While not given in this work, the conventional friction coefficient for any test situation is equal to the tangent of the slip angle. Thus for a 25 deg slip angle, the corresponding friction factor or coefficient is 0.46, etc.

### Ice

The results of tests on the ice (Figs. 3-17) start with a group of crutch tips (Figs. 3-6) that are alike in configuration but markedly different in scale. Employing as a basic concept a series of short cylindrical rubber studs, creating a stippled pattern, the manufacturer has provided a small version (Fig. 3,4), a medium (Fig. 5), and a large model (Fig. 6). Of these, performance is best for the medium model. In all cases, performance on ice is mediocre. While a comparison of the various versions ostensibly appears to be a test of "footprints" or contact area effects, it is likely that the differing stiffness of the bodies of the various versions is a complicating factor. In particular the large version is so stiff that the base is unable to flex readily. Thus the result of employing this version at an angle to the



ice is to place the entire tip at an angle to the surface, resting on only a few of the studs and preventing the development of a large "footprint." For this reason no clear conclusion concerning the value of "footprint" may be drawn from the series Figures 3-6.

A standard flat concentric-ringed cane tip (Fig. 7), with a small "footprint," is seen to perform on ice as well as any conventional device tested. Though all of the slip angles are below the desired 25 deg, most are above the observed 17 deg. Far larger concentric-ring concepts (Figs. 8,9, and 10), utilizing a recessed or dished interior and providing a relatively sharper rim, are not superior to the small, flat-ringed surface of the tip whose results appear in Figure 7. Small, dished, concentric-ring tips (Figs. 10 and 12) also do not perform as well as the flat-ringed tip.

The effect of air temperature above the ice may be seen in Figure 13 wherein similar runs were conducted at two different air temperatures. Note that the higher air temperature (in the 40's F) seriously reduces the slip angle obtainable at the ice as compared with the lower air temperature (in the 20's F). It appears that ice on the verge of melting is a more difficult design area than hard frozen ice. The item whose performance is given in Figure 13 is a particularly deep-dished, concentric ringed, large crutch tip, rather similar to the item tested in Figure 11. Performances of these items at the high air temperature are similar. Allowing for the effects of test temperature, the results of Figures 5,7,11 and 13 are roughly equal. This group contains the best results obtained from conventional devices. None of the tests on ice with the elevated air temperature meets the rule-of-thumb criterion (i.e., a slip angle of 25 deg) and probably the results shown in Figure 7 for low air temperature would deteriorate at higher air temperature.

All results discussed so far have dealt with brand-new devices. It also is of interest to evaluate worn devices by the same standard. Figures 16 and 17 give results of cane tips so badly worn and oxidized as to suggest junk. While the slip angle results obtained are mediocre, the performances are better than one might anticipate.

#### **A Special Metal Device**

Of all tested devices, the best performer on ice was the Monadnock Lifetime, a special metal device, given in Figure 15. The ice-gripping ability proved higher than the instrumentation capability, thus numerical data could not be obtained. However, all slip angles with this device are well above 30 deg under all axial-thrust loads and at both temperature conditions. The device relies on a sharpened steel ring to engage the ice. Once the ring is engaged, a large spring joining

the ring to the cane permits angular deflection of the cane shaft without loss of contact between the ring and the ice. Clearly, friction is not the basic operating mechanism; large values of penetration into the ice are obtained (on the order of 1 mm). Certain practical disadvantages of weight, bulk, risk of damaging floors, inconvenience of adjustment, and safety are developed in the discussion below; nonetheless it should be stressed that the performance of this device on ice is outstanding.

#### Soapy Wet Tile

As noted, two types of tile surface were tested; one relatively rough and one quite slick. Cane tips proved sensitive to surface roughness. Large differences in slip angle resulted as a function of surface type. Many cane tips equaled or bettered our desired 25 deg working angle on the rough quarry tile (Figures 6, 11, 12, and 15), while performance on the slick tile proved universally poor.

Performance on one type of tile does not associate with performance on the other. Thus the best-performing unit on the rough tile (Fig. 12) achieves but a mediocre showing on smooth tile. Presumably, different frictional mechanisms are at work on the varying surfaces.

The worn-out devices offer performances that are the equal of any (Figures 16 and 17). This may be attributable to the visible shredding of bits of material under load. Apparently in this manner fresh cane tip surfaces were constantly presented to the soapy tile, preventing any soap buildup on the cane tip.

The Monadnock Lifetime metal-ring device (Fig. 15) scraped and scratched the tile, doing some small damage to both cane tip and tile. Performance proved fairly good, under conditions hardly appropriate for this device.

### DISCUSSION

#### Some Cautions

The present introductory survey of static performance of currently available devices in challenging conditions is only a beginning. It does not test any single gross variable so systematically that firm conclusions can be drawn. Neither does it compare commercially available devices under a sufficiently wide range to permit formulation of specific prescription criteria or selection of a specific preferred make and model. This survey does not permit direct analyses of effects of hysteresis, modulus, or other properties of the material or

of a basic design; e.g., stiffness of structure, "footprint" under load, rings versus stippled base, "dishing" of rings, diameter, etc. It is hoped that subsequent studies may help to clarify questions on these points.

#### Some Assets

The present preliminary studies do confirm that numerous cane tips of substantially differing design and materials allow adequate safety on numerous *dry* surfaces, such as carpet, dry vinyl tile, or smooth firm plastic, as indicated by pilot tests showing slip angles well over 30 deg. Even on virgin snow, a few pilot tests on a layer one-quarter-inch thick over a parking lot surface at 32 deg F, with 10 lb axial load on the cane, showed slip angles over 30 deg for two examples of ring-type tips, one new and the other badly worn and oxidized.

On ice, many cane tips are believed to offer fair performance under conditions of low temperature; few appear safe at elevated air temperatures.

On rough tile flooded with soapy water, many cane tips have been shown to offer adequate performance. Unfortunately, no tested cane tip offers acceptable performance on slick tiles flooded with soapy water.

Table 1 summarizes the performance characteristics of all tested cane tips in a qualitative manner.

#### Special Hazards

Most of the tests were conducted on situations intuitively perceived as particularly hazardous; smooth ice (at air temperatures below freezing and especially at higher air temperatures encouraging a thin film of moisture) and a set of wet, soapy tiles comparable to certain showers, bathrooms, kitchens, restaurants, etc. during bathing or after mopping or accidental spills. Under some of these conditions the angle at which slippage occurred was sometimes below 3 deg. Clinically, the user thus would have to keep the shaft very nearly vertical and would need to avoid sloping terrain.



TABLE 1.—Summary: Qualitative Appraisal<sup>a</sup> of Performance

Cane tip	Test condition		
	Wet soapy rough tile	Ice rink ice	Wet soapy smooth tile
Safetee Crutshoe (small)	Fair	Poor	Inadequate
Safetee Crutshoe (medium)	Fair	Fair-Poor	Inadequate
Safetee Crutshoe (large)	Good	Poor	Inadequate
Davol 2916-1	Fair	Fair	Inadequate
Safe T Flex (Guardian 404)	Fair	Fair-Poor	Inadequate
Safe T Grips (Guardian 400)	Good-Fair	Fair-Poor	Inadequate
Nev-A-Slip 399	Fair	Poor	Inadequate
Preco	Good	Fair-Poor	Inadequate
Safe T Flex (Guardline 855)	Excellent	Poor	Inadequate
Nev-A-Slip 40	Good-Fair	Fair	Inadequate
Safe T Flex (Guardline 840)	Fair	Fair-Poor	Inadequate
Monadnock "Lifetime"	Good	Excellent	Poor
Worn unit (with rings similar to Nev-A-Slip 399)	Excellent	Poor	Poor-Inadequate
Worn Sherpa	Excellent	Fair-Poor	Poor-Inadequate

<sup>a</sup>Ratings are estimates of performance. Appraisals in descending order are: excellent, good, fair, poor, and inadequate.

Empirically, a user is usually aware of increasing risk of slippage on obviously slippery surfaces. The user then walks more slowly with shorter steps, decreased shear between shoes and surface, decreased rotary motions of the pelvis and legs with consequent decreased torques about the vertical axes through the feet, and more nearly vertical canes or crutches. In particular, the user fears a sudden slippage with sliding friction catastrophically lower than static friction. All the defensive or precautionary measures seem to increase energy consumption per unit of distance walked.

#### Special Devices

Despite the apparent advantage of high friction on ice from special devices (e.g., the metal ring and spring of the Monadnock or the many rings, spikes, or other aids disclosed in patents and other literature) many users are reluctant to use such devices. In some senses, use of the retractable metal devices is comparable to use of removable tire chains on an automobile. The situations allowing clear superiority of a relatively complex, bulky, and heavy device are

relatively rare for many users. Such situations often intermingle in a single trip with other situations where the device may scratch the floor, slip on terrazzo, or wear rapidly on concrete. The metal ring (Fig. 15) may be retracted upward by rotating it and its helical spring, but the user must balance himself somehow while sacrificing support to turn the cane or crutch upward to reach the ring to rotate it. Frequent adjustment is awkward and possibly hazardous. Perhaps the most serious drawback in using special devices is the risk of encountering *unexpected* small patches of dangerous terrain; e.g., ice with a film of water on a sunny day, in the midst of long stretches of safe dry concrete encouraging rapid gait with large shears and cane angles. Thus there are severe practical limitations to use of special aids, valuable as they seem to be for coping with certain major hazards.

#### Thrust Load

Thrust load was relatively easily controlled in these simple tests. Its influence, however, was not very clear. In some cases the slip angle increased appreciably with axial load. In others there was little change, or even some change from 10 to 20 lb followed by reversal at 30, and in a number of cases a substantial decrease in slip angle with increasing load. The reasons for this difference, presumably, lie in many differences among tips: the changing contact area or "footprint" as the rubber ridges or cylinders distort, the elastic bending or tilting of the entire structure with consequent changing angle of contact with the ground, or possibly a squeegee action of the rubber wiping the surface. Further experiments on more controllable designs are needed to separate variables.

#### Effects of Size

Figures 3-6 show tests of tips with superficially similar design (stippled base of small, short cylinders) but increasing size. The medium appears preferable. The three are *not* sufficiently geometrically similar, however, to permit precise comparison or firm conclusions.

#### Effects of Age

Normally one would tend to replace worn or aged, oxidized tips. Nevertheless a badly worn tip (with rings almost completely worn away) at least five years old performed modestly on ice at air temperature above freezing (Fig. 17). Both that tip and another of a different design (Fig. 16), which was so worn and oxidized that bits of rubber shredded away, performed surprisingly satisfactorily on

wet soapy tiles. In the absence of further data, however, it still seems prudent to replace worn tips.

#### Future

More systematic tests with better control of variables are contemplated. Durometer (hardness) and type of rubber or plastic, and variations of hysteresis and stiffness with temperature, will be studied. Design affects "footprint," squeegee action, and inclination of the base. Crutches clearly apply far larger loads than those tested thus far. Perhaps novel designs can be developed.

#### CONCLUSIONS

A variety of commercially available cane and crutch tips were tested on surfaces of ice and soapy tile under varying axial (thrust) loads. The output measurement consisted of the angle between the vertical and the cane axis at which slip occurred. It was learned that:

1. From the viewpoint of a user, a minimal slip angle of roughly 25 deg is desirable.
2. On ice-rink ice, a number of cane tips approach the desired slip angle under conditions of low temperature; fewer appear safe at elevated air temperatures. Only one of the tested devices appears truly safe under any ice condition.
3. On rough tile flooded with soapy water, some cane tips offer adequate performance. However, no tested cane tip offers acceptable performance on slick tile flooded with soapy water.
4. There appears to be no simple relationship between the slip performance of a cane tip on ice-rink ice and that developed on soapy wet tiles.
5. No simple relationship between thrust load and slip angle emerged. Similarly, no simple relationship between contact area and slip appeared in the data.

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**VETERANS ADMINISTRATION PROSTHETICS CENTER  
RESEARCH REPORT**

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- c. Mortensen Safety Knee
- d. Nitschke-Tindall Ankle Rotator

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2. Lower-Limb Components

a. LAPOC Safety Knee

b. Multiplex Mark II Above-Knee Prosthesis

III. THE VAPC CLINIC TEAM

I. DEVELOPMENT AND EVALUATION

A. Prosthetics

1. Lower Limb

a. *Graphite-Epoxy Shank for Partial Thigh Endoskeletal Prosthesis.* Since the last progress report (BPR 10-27) the knee casting for the knee joint has been completed. When the prototype model is received from the manufacturer, the system will be evaluated.

The graphite SACH foot keels were produced by Browning Manufacturing Co., Morgan, Utah, and the feet were manufactured by the Kingsley Manufacturing Co., Costa Mesa, California. The feet are now ready to be attached to the shank.

b. *Prosthetic Skin.* The "prosthetic skin," i.e., cosmetic technique using cosmetic covers of soft polyurethane foam, developed under a VA contract by George Washington University (BPR 10-26, p. 217), is being used routinely at the VAPC for external cosmetic covers for the Multiplex system. The covering is also useful for below-knee endoskeletal covers made of rubber or soft polyurethane foam (Fig. 1). A durable cosmetic cover in any of eight different shades can be produced. A videotape describing the entire process is available upon request from the VAPC in New York City.

c. *Mortensen Safety Knee.* The Mortensen Safety Knee, designed and developed by the Kingsley Manufacturing Company, Costa Mesa, California, is a safety knee with a spring-backstop installed in a wood and urethane foam knee shin setup. It has a conventional wood shin with a standard knee bolt and side straps. The knee block is cast of high-density structural polyurethane rigid foam. The spring-backstop serves both as an extension stop and an extension assist; extension bias is adjustable.

Stance phase knee-locking action is accomplished by two friction brakes that clamp to the knee bolt when weight is applied to the prosthesis. Swing-phase resistance can be increased or decreased by tightening or loosening the friction brake adjustment screw. Due to the stability of the knee, the recommended alignment procedure is started with the knee center slightly anterior to the ankle center.



FIGURE 1.—Prosthetic skin for below-knee endoskeletal covers.

The Mortensen Safety Knee is included in the VA National Artificial Limb Contract.

d. *Nitschke-Tindall Ankle Rotator.* The Nitschke-Tindall Ankle Rotator, designed and developed by the Rochester Orthopedic Laboratories, Rochester, New York, is an axial rotator. The mechanism includes a rubber bumper located in the posterior section that returns the foot to a neutral position after rotation occurs. Amputee sub-

jects fitted in our Patient Care Service commented on the reduced weight as compared with other rotators. This rotator appears to be more simply designed than other rotators.

## 2. Upper Limb

a. *Improved Suspension for Wrist Disarticulation Prostheses.* For years, amputees with wrist disarticulations or transcarpal amputations were fitted by conventional methods: with flexible hinges and figure-eight harnessing to control the terminal device. Newer socket designs, such as the supracondylar suspension system, have provided more freedom by eliminating the need for a harness. However, this type of socket limits elbow flexion and extension, and eliminates wrist supination and pronation.

The Patient Care Service is developing a suspension system that utilizes a silicone rubber liner for long below-elbow and wrist-disarticulation prostheses. The liner, which is similar to the closed Syme prosthesis, is a separate component of the system and can be removed. The friction between the liner and the socket walls provides additional suspension to the rubber insert above the styloid process.

This system was first fitted to a transcarpal amputee who had active wrist flexion and extension, normal muscle strength, and full range-of-motion throughout the limb. He was able to flex his wrist to close the hand, and extend his wrist to open the hand. Since the friction between the liner and socket walls, together with the effect of the built-up area just proximal to the styloids, provided adequate suspension, no harness was needed. The patient could perform all activities without inadvertently opening or closing the hand. The suspension system could withstand a pulling force of up to 50 lb. After 1 year of wear, this patient experienced no skin irritation or other adverse reactions from using the system.

We are currently attempting to fit a wrist disarticulation patient with a similar system, except that this unit will be myoelectrically controlled instead of switch controlled, and a new myoelectric hook, developed by the VAPC, will be used.

b. *The Northwestern University Synergetic Hook.* The VAPC and RCP are conducting a field evaluation of a myoelectrically powered prosthetic hook developed at Northwestern University. Participating in the study are the VAPC, RCP, and the VA Hospitals at Miami, Atlanta, Houston, West Virginia, and Boston.

Twelve hooks are being tested by patients for function and durability. Also being tested are its range of applicability, and the ease of installation, maintenance, and repair. The program is being con-



ducted over a period of 3 months. The results and recommendations will be sent to Northwestern University.

## B. Orthotics

### 1. Upper Limb

*Counter-Force Elbow Orthosis.* In previous issues (BPR 10-25 and 10-26) we have described a functional elbow orthosis used for incomplete brachial-plexus-injury patients. This device (Fig. 2) utilizes a shoulder cap to stabilize the shoulder and upper arm, especially during elbow flexion. A gas "spring" cylinder with strong pulling action effectively replaces weak biceps muscles. A small wrist cuff lifts the hand into position.

Patients with near-normal hand function and elbow extensors, but poor or zero elbow flexors, are ideal candidates for this system because the shoulder cap provides all the necessary support and suspension and no shoulder motion is required. Several units are scheduled to be fabricated and distributed for further evaluation at other VA stations.

### 2. Lower Limb

*Orthotic Transverse Rotator.* Mr. John Glancy, Indiana University Medical Center, has developed a lightweight ( $\geq 12$  oz) transverse rotator for lower-limb orthoses. The rotator consists of a nylon casement or housing that is inserted into a shoe sole to permit the wearer to glide his body forward by rotating on a Teflon surface in the transverse phase. A long steel shank attaches the rotator to the shoe. The rotator reduces friction to a low level at the shoe-floor interface and thereby provides external transverse rotation to substitute for lost motion that normally occurs in the subtalar joint.

Four rotators have been fitted to various orthotic users and preliminary reports are favorable. Patients find it easier to ambulate and make left or right turns. The durability of the device over a 3- to 6-month period is currently being tested.

## C. Spinal-Cord-Injury Rehabilitation

### 1. Environmental Control Systems

a. *The VIP-100 Speech Recognition Environmental Control System.* The VIP-100 Speech Recognition Environmental Control System, manufactured by Threshold Technology, Inc., Delran, New Jersey, is a voice-operated system designed for quadriplegics. An initial checkout and operational test of the system has been



FIGURE 2.—Counter-force elbow orthosis.

completed, and the device is currently being evaluated at the VA Hospital, Castle Point, New York.

b. *Johns Hopkins Remote-Manipulator* (also known as the JH Medical Manipulator/Worktable). The Johns Hopkins Remote-Manipulator (Fig. 3) was designed and developed by the Johns Hopkins University Applied Physics Laboratory, Baltimore, Md., for disabled persons with little or no use of their upper limbs. Used in conjunction with a worktable, the Remote-Manipulator provides its user with such capabilities as self-feeding with a spoon or fork, handling and reading certain magazines and newspapers, turning appliances and environmental controls on or off, and operating such pushbutton-controlled devices as a touch-tone telephone, an electric typewriter, a desk calculator, and a tape recorder.

The Remote-Manipulator is currently undergoing field and laboratory tests at the Castle Point, New York, VA Hospital. After these tests, the device will be tested at the University of California Biotechnology Laboratory in Los Angeles.



FIGURE 3.—Johns Hopkins Remote-Manipulator.



c. *Prentke Romich ECU-1 Environmental Control Unit.* The Prentke Romich ECU-1 (Fig. 4), previously reported on in BPR 10-27, is manufactured and distributed by the Prentke Romich Company, Shreve, Ohio. This environmental control unit allows quadriplegics to operate various electrical appliances via single-switch or dual-switch activation. Several units have been evaluated to determine their safety, effectiveness, and usefulness.

Several subjects, both homebound and hospital patients, participated in the clinical trials. The consensus reached by the participants was that the system was useful, and that operating the system was easy to learn.

d. *Remote Outlet.* The Remote Outlet is commercially available from General Teleoperators, Inc., Downey, California. The device consists of a 125 V a.c. receptacle that provides power for appliances, such as radios or lamps, that are located up to 15 ft (4.57 m) away from an environmental control unit. The device is plugged into a standard 125 V a.c. wall socket; it is controlled by a low voltage control line from the environmental control unit.

Several Remote Outlets are currently undergoing clinical trials at the VA Hospital, Castle Point, New York.

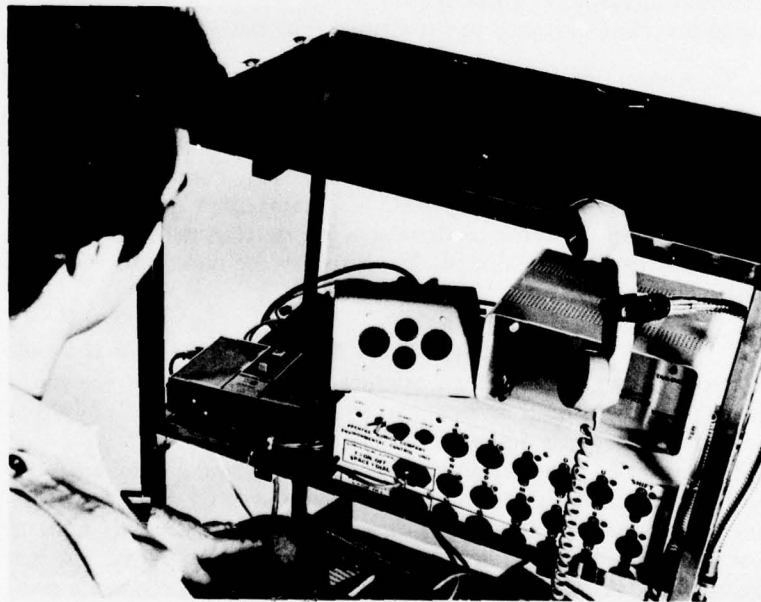


FIGURE 4.—Prentke Romich ECU-1.

c. *Adapted VAPC Hospital Environmental Control System for Home Use.* An environmental control system was modified for a legally blind, paralyzed individual who is able to distinguish between colors. The user activates or deactivates an appliance by sipping or puffing on a pneumatic tube. This action also illuminates indicator lamps, sequentially, on the Monitor Unit that correspond to the appliances being activated. To operate the system, the user must memorize a code that is related to the number and color of lamps on the Monitor Unit. White and green are used for convenience appliances and marginally essential appliances, such as electric beds and night callers. Red is used for emergency devices: an automatic telephone dialer that transmits prerecorded messages, the VAPC Patient Alarm that provides an audiovisual alarm signal within the home, and an outdoor alarm that alerts the neighbors.

Twelve selections are available: these are being utilized to activate an audio-visual alarm in the family's living room, and an audio alarm in the spouse's bedroom, a color television set, a radio, a speaker phone, a lamp in the user's bedroom, a "talking books" tape recorder, an alarm to summon family members who may be outside, and an automatic telephone used in an emergency to alert police, fire department, and neighbors, or to request medical aid through a pre-recorded message. The completed device has been in operation for 5 months; clinical results are favorable thus far.

## 2. Communication Aids

a. *Prentke Romich Intercom System.* The Prentke Romich Intercom System (Fig. 5), designed and developed by the Prentke Romich Co., Shreve, Ohio, enables a user to selectively communicate with 2 other stations. Individual privacy is maintained by requiring the remote-station operator to depress a pushbutton manually when he is transmitting. Clinical trials are currently being conducted at the Castle Point, New York VA Hospital.

b. *VAPC Remote Alarm.* The VAPC Remote Alarm is a radio-controlled alarm designed to operate the VAPC Patient Alarm. The device may be used to indicate an emergency to advise family members of the patient's desire to reenter his home.

It consists of a radio transmitter, a receiver, and a 115V a.c. power outlet. The transmitter can be controlled either by a microswitch or pneumatically. The receiver is designed to insure that an alarm cannot be terminated by a second signal from the patient-operated transmitter. A family member or attendant must depress a switch located on the receiver to deactivate the alarm. The device is currently undergoing clinical evaluation in the homes of two outpatients.

c. *ZYGO Model 16 Communication Board.* The ZYGO Model 16 Communication Board assists paralyzed, speech-impaired (dysarthric) patients to communicate. Veterans with advanced amyotrophic lateral sclerosis or multiple sclerosis may be candidates for the device. It is commercially available from ZYGO Industries, Inc., Portland, Oregon.

The device consists of an actuator and a message board. The actuator may be a sensitive pneumatic switch, a microswitch with an acceptably large surface-contact area, or a microswitch with a long lever arm. The message board consists of a 4 in by 4 in matrix with a lamp located in each square, and sufficient space to indicate, in pictorial or written form, preselected messages.

The ZYGO Model 16 Communication Board is currently undergoing clinical evaluation.

d. *VOTRAX Handi-Voice System.* The VOTRAX Handi-Voice System is commercially available from Vocal Interface Division, Federal Screw Works, Troy, Michigan. It consists of three sections: an input actuator, a minicomputer, and two output speakers. The input actuator is available in either a touch-tone pad or a keyboard configuration. The touch-tone pad provides an audio output when associated pictures or words on the board are depressed lightly. The

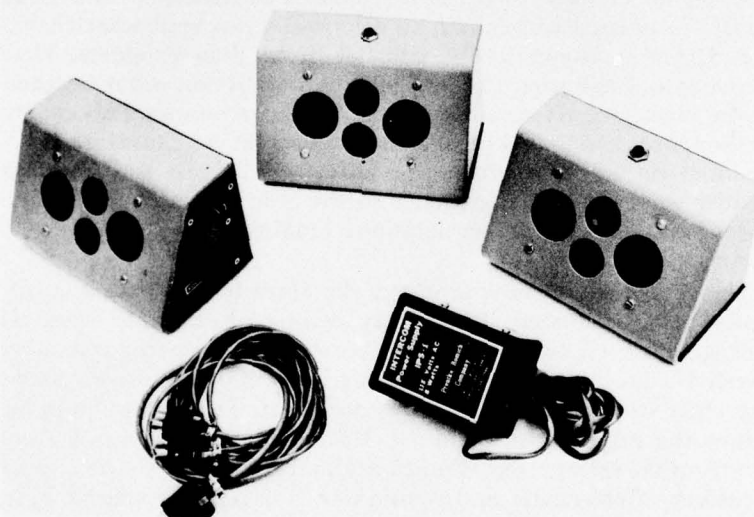


FIGURE 5.—Prentke Romich Intercom System.



keyboard, which resembles a hand-held calculator, provides an audio output when the appropriate numerical code has been selected. The keyboard can also be operated by those who are unable to manipulate their fingers or a mouthstick. A 3-digit numeric system allows selection via a microswitch or a sensitive microphone that is worn next to the user's larynx.

The minicomputer, which is controlled by the input actuator, allows for adjustment of the speech rate, audio level, and pitch. It permits reprogramming the language of this device to meet the needs of different users. Approximately 440 words, phonemes, phrases, and alphabet characters are available on the unit.

Up to 32 entries can be recalled. This allows the user to insert messages into a memory and have the unit repeat them on demand. The operator may insert a short paragraph of questions or statements that may be played back when the doctor or therapist visits the user.

Words or sentences can be repeated indefinitely: this should aid the listener if a word is not clear. Pauses between phrases, words, or sentences can be inserted by the user. The VOTRAX Handi-Voice System is currently undergoing clinical evaluation.

### 3. Mobility Aids

a. *Electronic Power Conversion Kit for Wheelchairs.* The Electronic Power Conversion Kit for Wheelchairs (Fig. 6), previously reported on in BPR 10-26, is designed to convert most American models of manual wheelchairs to electrically powered wheelchairs. The device is commercially available from Solo Products, West Sacramento, California. The original Solo Mark II unit was redesigned by the manufacturer to eliminate certain shortcomings. Laboratory performance testing had been completed on the original Mark II kit mounted on Rolls, Stainless Specialty, and Everest and Jennings Premier wheelchairs. Performance of the Solo package on all three wheelchairs was good; acceleration, braking, and stability were found to be satisfactory.

The manufacturer now produces the Mark III Kit, which is currently being evaluated. Preliminary testing of the Solo Mark III package has been completed and laboratory performance tests have revealed a problem with the dynamic braking of the drive system. The chair stops abruptly and does not coast. This abrupt stopping throws the subject forward in the chair, and he experiences discomfort from the safety strap. Clinical trials are continuing to determine the safety, effectiveness, and usefulness of this power conversion kit.

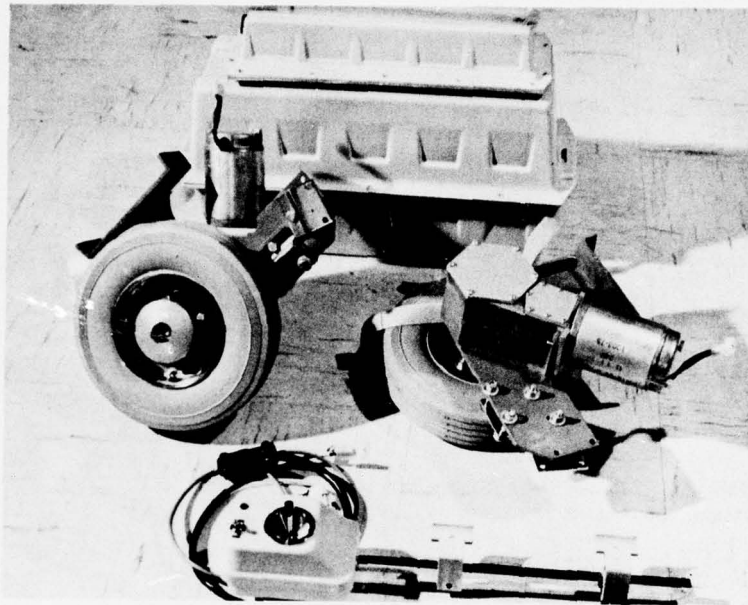


FIGURE 6.—Components of the Solo electronic power conversion kit for wheelchairs.

b. *Electric Back-Recliner Kit.* The Electric Back-Recliner Kit (Fig. 7 and 8) is commercially available from General Teleoperators, Inc., California. It is designed to convert powered wheelchairs with a full or semi-reclining back (particularly the Everest and Jennings 12-V electric wheelchair with full-reclining back) to electrically powered full back-recliners. The device permits the wheelchair-bound patient to adjust his position, through graduated steps, from an upright seated position to a full-reclining position and back again without assistance. One unit is currently being evaluated on a special powered wheelchair at the VA Hospital, Castle Point, New York.

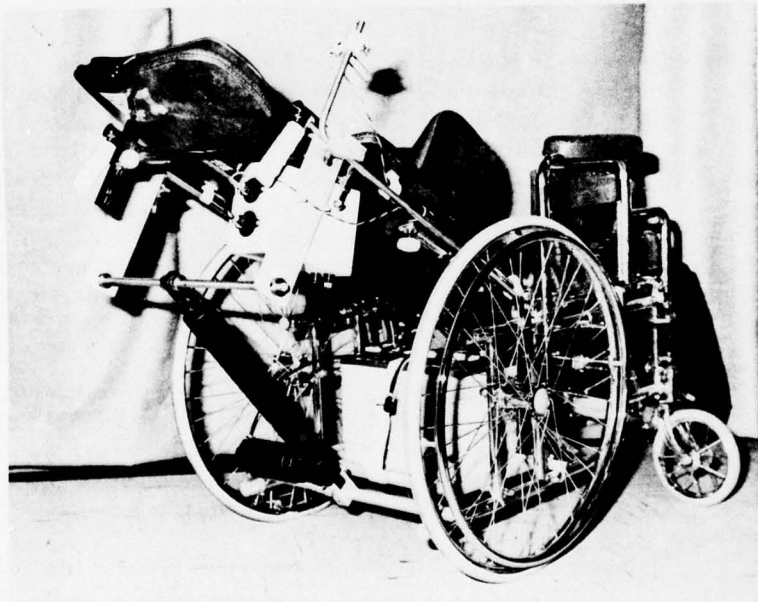
c. *Chin Control Powered Swing Away.* The Chin Control Powered Swing Away (Fig. 9) is commercially available from General Teleoperators, Inc., Downey, Calif. This device is designed to move the chin control away from the wheelchair occupant when the wheelchair is stationary, or back into position when the wheelchair is being driven.

Two units currently undergoing clinical trials indicate the Chin Control Powered Swing Away is quite responsive and easy to activate.



FIGURE 7.—Electric Back-Recliner Kit;  
at right, upright position.

FIGURE 8.—Electric Back-Recliner Kit;  
below, reclining position.





Patients found it a convenience to have the chin control out of the way while eating or reading. Results indicate that the multipositional bracket must be tightened securely so that driving over door sills or rough terrain does not cause the chin control to move beyond the user's reach.

d. *Pyramid Folding Quad Cane.* The Pyramid Folding Quad Cane (Fig. 10) is available from Edco/Pasco, Inc., Passaic, New Jersey. The device is a walking aid for patients who need a walker but require

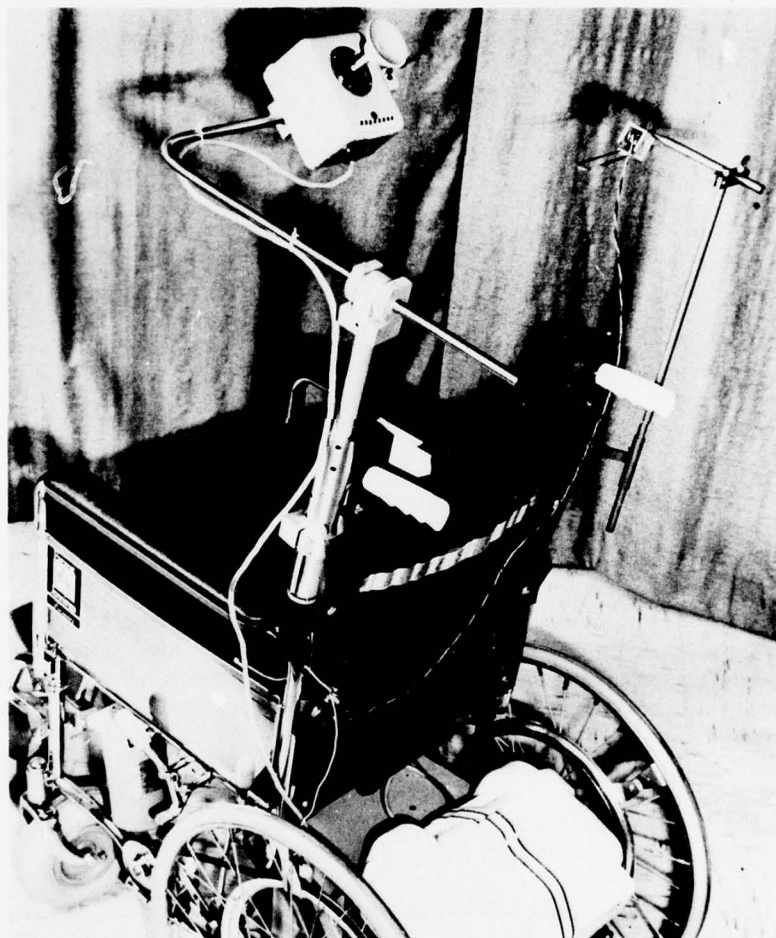


FIGURE 9.—Chin Control Powered Swing Away.

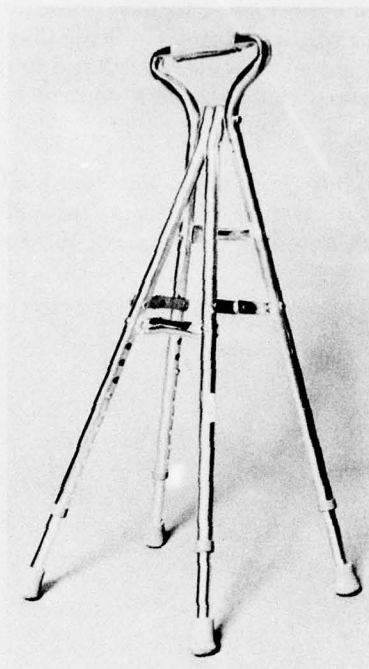


FIGURE 10.—Pyramid Folding Quad Cane.

more support than that provided by a standard cane or standard quad cane. It is intended for use by cardiovascular accident patients, patients with healing hip fractures, and lower-limb amputees with prostheses.

The height of the cane is adjustable, as are the depth and width of the base. By increasing the size of the base, greater support and stability for taller patients is obtained. The closed handle of the cane concentrates the patient's weight over the base of the cane for greater safety.

The cane is being clinically evaluated at the Castle Point, New York, and Omaha, Nebraska VA Hospitals. Preliminary results indicate that the Pyramid Folding Quad Cane is indicated for patients who have poor balance and coordination.

e. *Sun Industries Curb-Climbing Electric Wheelchair.* The Sun Industries Curb-Climbing Electric Wheelchair (Fig. 11) was provided for evaluation by the J.A. Preston Corp., New York City. This device

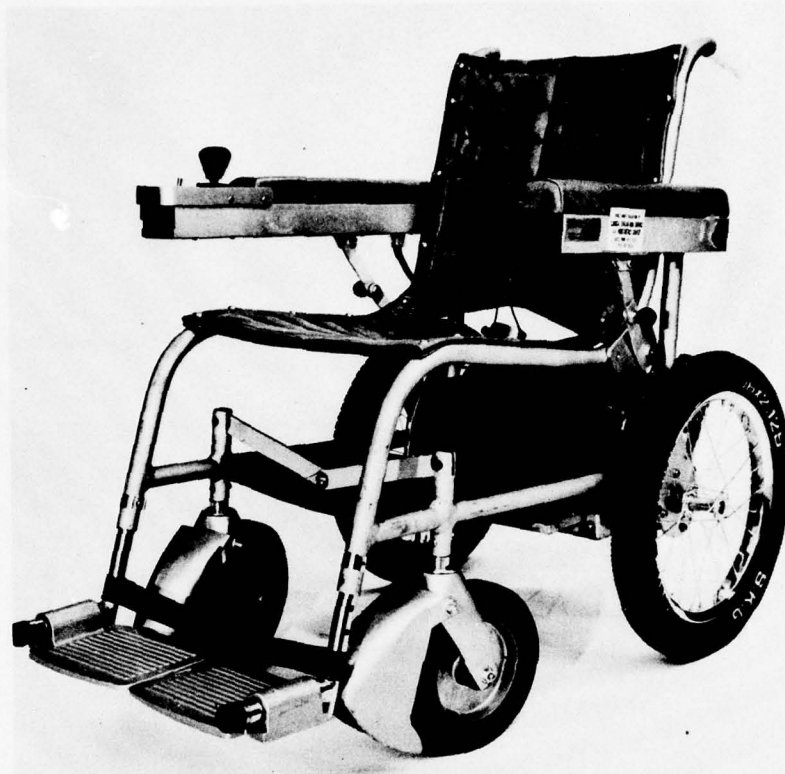


FIGURE 11.—Sun Industries Curb-Climbing Electric Wheelchair.

is manufactured by Japan Sun Industries, Tokyo, Japan. According to the manufacturer, this motorized wheelchair is capable of ascending and descending 3-in (7.62-cm) curbs and negotiating inclines of 20 deg and more. The wheelchair features a hand-operated joystick-controlled microswitch array and a high-low speed-selection switch. Power is derived from two 12-V, 24-Ampere-hour batteries.

Run-over sleeves on front casters help to surmount curbs. The user approaches the curb squarely and with sufficient speed so that the run-over sleeves clear the curb. The runover sleeves then raise the front casters onto the curb. (The rear tires are large enough to mount curbs without run-over sleeves.)

When tested, the wheelchair was able to negotiate 3-in (7.62-cm) curbs and a cement curb that was 4 in (10.16 cm) high with a rounded



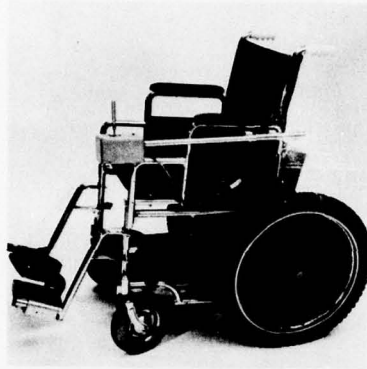


FIGURE 12.—GenTel Motor-in-the-Hub powered wheelchair.

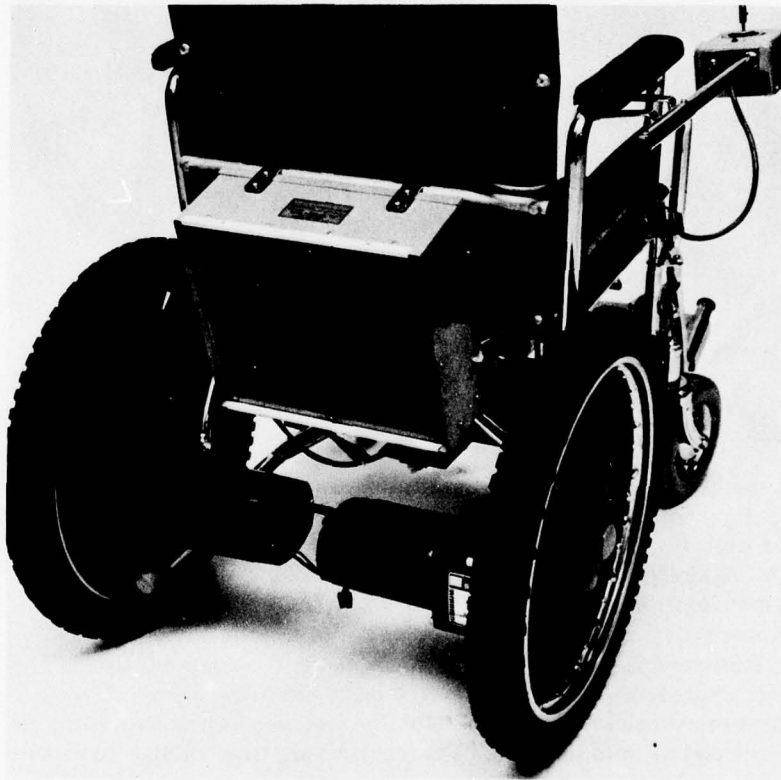


FIGURE 13.—Motor-in-the-Hub powered wheelchair has dual 12 V battery power and direct rear-wheel, drive-gear transmission.

edge that had a 1-in (2.54 cm) radius. Clinical trials and laboratory performance tests are currently being conducted to determine the safety, effectiveness, and usefulness of this wheelchair.

f. *GenTel Motor-in-the-Hub Powered Wheelchair.* The GenTel Motor-in-the-Hub Powered Wheelchair (Fig. 12) is commercially available from General Teleoperators, Downey, California. Of the units currently being evaluated at the VA Hospital, Castle Point, New York, one has an Everest and Jennings electronic control package and the other has a General Teleoperators control package. In both units, power is supplied by two 12V batteries and is applied to the rear wheels (Fig. 13) by direct-drive gear transmission. They are operated by proportional, two-speed, joystick controls.

Preliminary laboratory testing of the wheelchair has shown that the average maximum speed, with a 155 lb (70.31 kg) test subject, is approximately 4.71 m/h (7.58 km/hr).

Both Motor-in-the-Hub Powered Wheelchairs were evaluated by three subjects: two quadriplegics and one multiple sclerosis patient. The subjects liked the power, speed, and maneuverability of the device, particularly outdoors. The device functioned well indoors, outdoors, and on the type of terrain too difficult for most other powered wheelchairs. The knobby black-carbon rear tires provided excellent traction outdoors and caused no damage indoors; they did, however, track more dirt inside than other types of wheelchair tires.

It was suggested to the manufacturer that future models be supplied with wide, non-marking grey tires. Several other recommendations for improvement were made. Further clinical trials of improved models will be conducted.

g. *National Wheelchair.* The National Wheelchair (Fig. 14), produced by National Welded Products, Redwood City, California, is a battery powered, electronically controlled wheelchair. Several modifications have been introduced to the wheelchair, since it first appeared as the Advanced Wheelchair reported on in BPR 10-22. The National Wheelchair is designed for indoor and outdoor use by quadriplegics and other severely handicapped persons, particularly outdoors.

The rate of speed of the National Wheelchair with a 158 lb (71.67 kg) test subject was approximately 3.6 m/h (5.8 km/h) in the slow mode, and 6.8 m/h (11 km/h) in the fast mode. With power off at maximum low-speed mode, the chair coasts approximately 54 in (137.16 cm), and approximately 99 in (251.46 cm) in the high-speed mode. With a 158 lb (71.67 kg) test load and with the brake disengaged, the chair rolls down a test ramp of approximately 3 deg.

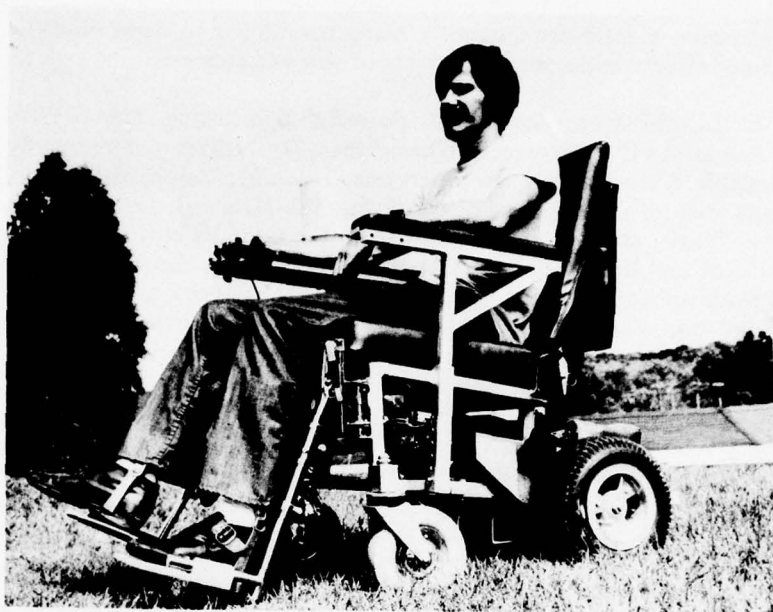


FIGURE 14.—National indoor-outdoor wheelchair.

With the brake engaged, it rolls downhill on a 13 deg incline. Maximum ramp-climbing ability with a 158 lb (71.67 kg) test subject at low speed is 9.5 deg, at high speed, 13 deg.

The chair is quite powerful and comfortable during operation, and performs well outdoors on grassy surfaces and on hard surfaces. But the rear wheels slip on loose dirt and it seems to need more weight in the rear. Maneuverability is good and there are a number of useful secondary features. Further clinical trials are required, however, to fully determine the safety, effectiveness, and utility of the National Wheelchair.

h. *Insta Gaiter*. The Insta Gaiter (Fig. 15), available from Instrument Components Company, Inc., Mentor, Ohio, is an electromechanical kit designed to convert standard manually propelled wheelchairs into electrical, joystick-operated, proportionally controlled wheelchairs. It is portable and can be easily disassembled and reassembled, and can be carried in a car. The evaluation of this unit is being delayed, pending necessary repairs by the manufacturer.



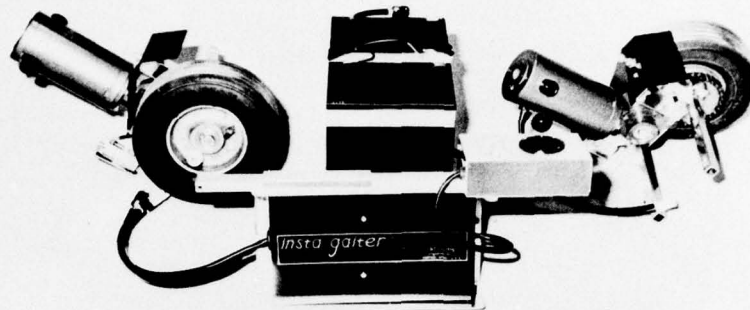


FIGURE 15.—Insta Gaiter.

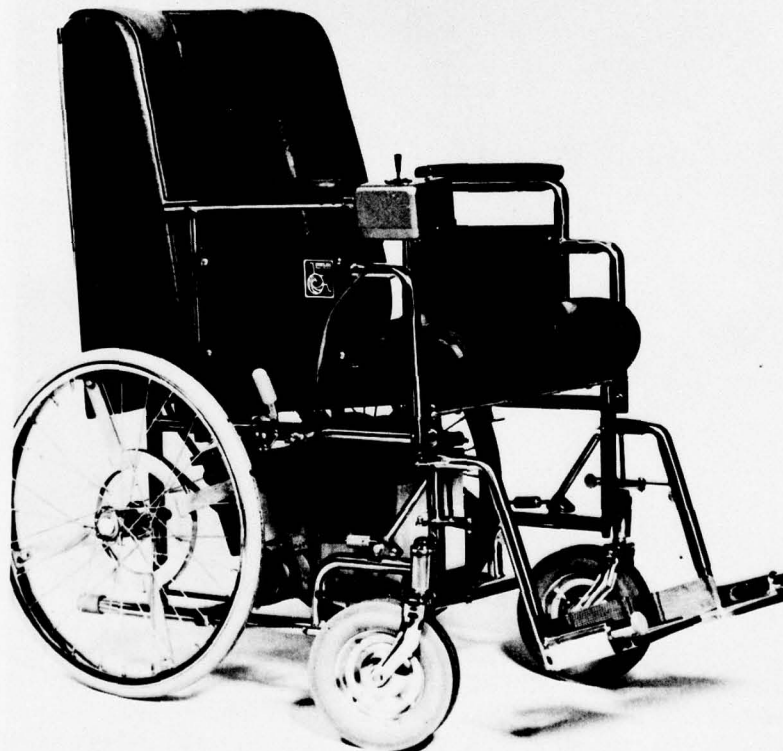


FIGURE 16.—SMP Electra-12 wheelchair.

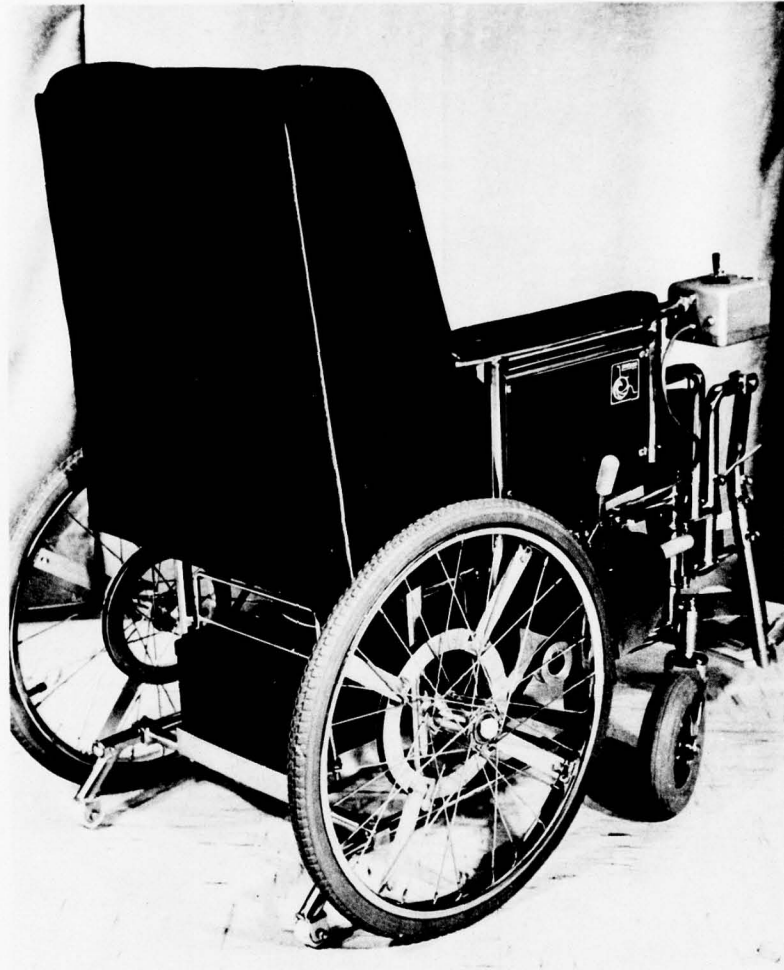


FIGURE 17.—SMP Electra-24 wheelchair.

i. *Stainless Medical Products Electric Wheelchairs.* The Stainless Medical Products (SMP) 12V and 24V electric wheelchairs (Figs. 16 and 17) (SMP Electra-12 and SMP Electra V-24, respectively), previously reported on in BPR 10-26, are manufactured and marketed by the Stainless Medical Products Company, Santa Ana, California. The evaluation results show that while the SMP Electra V-12 generally performed satisfactorily, the controller circuit should be modified

by the manufacturer to ensure against battery drain when the unit is in the "off" mode.

The SMP Electra V-24 wheelchair also performed reliably during the evaluation period: speed, ramp-climbing ability and overall performance, particularly on moderately uneven terrain, were excellent. The pneumatic tires on all four wheels undoubtedly added to the comfort and performance of the wheelchair. The SMP Electra V-24 is also recommended, particularly for those who require high-performance wheelchairs (e.g., for vocational or educational purposes). However, care should be taken that the high performance and seating configuration of this vehicle clearly matches the particular needs of the wheelchair occupant.

j. *Adult Powered Tricycle.* Non-powered adult tricycles are becoming increasingly popular among elderly persons who use them for exercise, recreation, and common activities of daily living. At the St. Albans, New York, VA Extended Care Center, one such item is now routinely used for recreation and exercise. Certain elderly veterans with weak lower limbs or amputations would like to take advantage of such an item, but are generally precluded from using them due to limited attendants.

An electrically powered adult tricycle, purchased from the Lyman Electric Co., Bridgeport, Conn., was modified to provide variable speed and adjustable seat height. The vehicle incorporates a dual brake system, and speed is modulated by a brake-type caliper handle operating on a pulse width controller: increased speed is achieved by squeezing the handle. The battery charger is a separate unit to preclude potential shock hazard; improved wiring and a heavy-duty relay increase the reliability of the tricycle.

The tricycle may be used as a totally powered system, or simply as a foot-propelled, or foot-propelled with power assist, system during warm weather. The latter method permits an above-knee amputee to pedal the tricycle for up to 50 miles. If continued interest in the vehicle is evident, additional units will be obtained for use at other VA facilities, particularly for cardiovascular patients.

k. *VAPC Powered Ambulator.* The VAPC Powered Ambulator is primarily an evaluation tool, to determine the potential benefits of a powered mobile platform that keeps its occupant in a standing position. Its possible usefulness in vocational applications appears promising for those who practice drafting or work in a machine shop, and in conducting activities of daily living. Its therapeutic value with respect to improved blood circulation, kidney function, retention



of calcium in the bones, and psychological advantages will also be investigated.

The original ambulator was fitted with small front caster wheels which occasionally prohibited the occupant from traversing small obstacles such as door saddles, a problem easily overcome by replacing them with 5 in diameter caster wheels.

If the current design demonstrates general acceptance by patients, two or three additional models will be assembled and evaluated at other VA facilities.

l. *Ausmus Moto-Stand*. The Ausmus Moto-Stand developed by the Ausmus Manufacturing Co., Independence, Missouri, is intended for paraplegics in vocational environment where standing mobile frames may be helpful.

This ambulator incorporates a three-wheel support with a single powered wheel located at rear, a 12V battery, a mechanical brake, a low/off/high toggle switch for speed selection, and a rocker switch to select forward and reverse directions. Restraining straps, to assist torso stability, are located around the level of the buttocks and the top of the T-Bar Handle.

The Ausmus Moto-Stand is currently being evaluated at the Castle Point, New York VA Hospital.

m. *Plantar and Dorsiflexion Foot Plates for Wheelchairs*. New VAPC-designed plantar and dorsiflexion foot plates for wheelchairs incorporate a simple joint, adjacent to the anatomical ankle, to assure proper foot orientation. This enhances comfort and stability for the occupant. One unit is currently being evaluated at the St. Albans, New York, VA Extended Care Center.

n. *Illuminated Reachers for Wheelchairs*. Elderly persons with cataracts commonly use reachers to help them grasp items on a shelf or the floor. A simple modification to the common mechanical reacher is a small lamp at the tip of the device, to illuminate the area of interest. The lamp is normally operated by gripping the handle and squeezing the trigger which operates the grasping function of the reacher. Two VAPC-designed units are being evaluated.

o. *LEM Power Chair*. The LEM Power Chair (Fig. 18), manufactured in Vicenza, Italy, is imported by the French-Italian Marketing Corp., Great Neck, New York, and distributed through medical equipment distributors throughout the United States. It is an electric wheelchair for paraplegics, amputees, and other handicapped individuals who are unable to ambulate but have retained the use of their

arms and hands. The LEM is unique in that the user can manually swivel the support base completely around. Two units are being evaluated.

4. *Body Support Systems*

a. *Blair Bed*. The Blair Bed (Fig. 19), previously reported on in BPR 10-24, and developed by Reed F. Blair, Inc., Pittsburgh, Penn-



FIGURE 18.—LEM Power Chair.

sylvania, is intended to permit a flow of air over a bedridden patient's back to prevent or treat decubitus ulcers.

Clinical evaluation demonstrated that the Blair Bed accomplishes the purpose of allowing aeration of the patient's back. However, the effect of pressure created by the hammock when the patient is raised is a disadvantage to the healing of the patient's ulcers.

b. *Wheelchair Cushion Study.* The current Wheelchair Cushion Study is, again, a joint effort of Dr. George Van B. Cochran's Biomechanics Laboratory at the Helen Hayes Hospital, and the VAPC Clinical Evaluation Service at the Castle Point VA Hospital. (See "Experimental Evaluation of Wheelchair Cushions: Report of a Pilot Study," BPR 10-20, pp. 29-61.) Subjective patient data on the short-term performance of wheelchair cushions are being collected in clinical trials conducted at the Castle Point VA Hospital. This information will be correlated with the laboratory data from the Helen Hayes Hospital. The results should provide an approved selection of cushions.

Twenty-three different types of cushions are currently undergoing clinical and mechanical testing. These cushions represent a variety of latex and polyurethane foams, gels, impact absorbing, and water types. The patients participating in this study are on wheelchair/bed

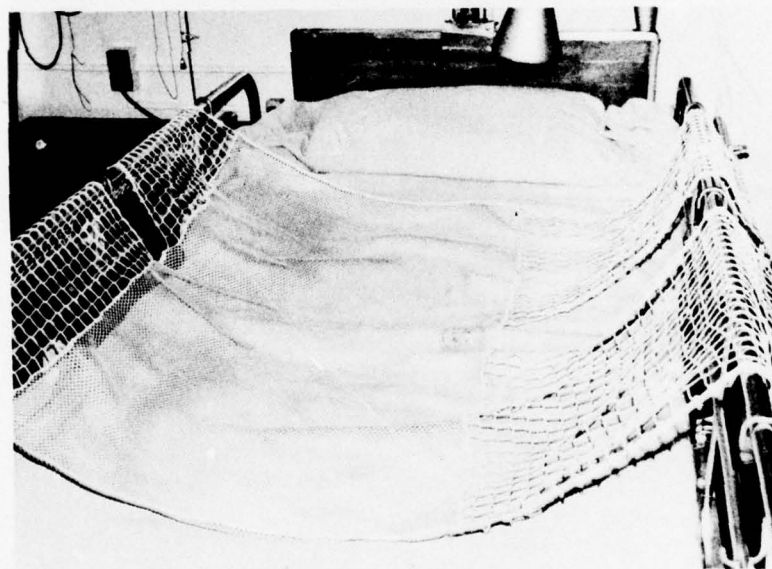


FIGURE 19.—Blair Bed.



status, with partial or complete sensation over the buttocks area. They are dependable and well-motivated. The clinical trial consists of 3 hours of use of each test cushion by each subject. The subjects are limited to one test-cushion trial per day. Each subject will test each of the 23 cushions, so that an average response can be obtained. All results from the clinical trials are being recorded by Dr. Cochran. No conclusive clinical findings are available at present.

c. *Medpro Chair Flotation Cushion.* The Medpro Chair Flotation Cushion (Fig. 20), distributed by Medpro, Inc., of East Brunswick, New Jersey, is a pressure distribution flotation cushion that is designed to prevent decubitus ulcers on wheelchair-confined patients.

It basically consists of two polyvinyl-chloride sections and an elastic cover. An inflatable, rectangular-shaped, tubular air frame surrounds the main body, which stores approximately 1.8 gal (6.81 l) of water. Guidelines and applications for the use of this cushion will be determined through further clinical trials.

d. *RoHo Balloon Cushion.* The RoHo Balloon Cushion (Fig. 21), developed and distributed by RoHo Research and Development, Inc. Belleville, Illinois, is used to distribute body weight, in a seated position, to reduce body tissue pressure and thereby either prevent or help heal decubitus ulcers.



FIGURE 20.—Medpro Chair Flotation Cushion.

The cushion consists of 72 interconnected, yet freestanding, balloon elements attached to a neoprene rubber base (Fig. 22), and pressure varies between 30 and 50 mmHg. Individual balloons can be deflated and tied off to prevent contact with sensitive portions of the body or areas where decubitus ulcers have already formed.

One Balloon Cushion is undergoing laboratory testing at the Helen Hayes Rehabilitation Center, Haverstraw, New York; another is undergoing clinical trials at the Castle Point, New York VA Hospital. Further clinical trials are required to determine applications and guidelines for this device.

e. *E-Z Patient Turning System.* The E-Z Patient Turning System, Model 520 (Fig. 23), commercially available from Physical Aids, Inc., El Cajon, California, is an inflatable, two-section air mattress designed to prevent decubitus ulcers by turning bedridden patients from a supine position to a maximum position of approximately 45 deg.

A laminated air mattress of vinyl and nylon is sealed down the center to create two halves. A small 20-lb (9.07 kg) air pump plugs into a standard 110V a.c. wall socket to inflate or deflate the air mattress: each half of the mattress is inflated or deflated independently. The pump shuts off automatically when the mattress is fully

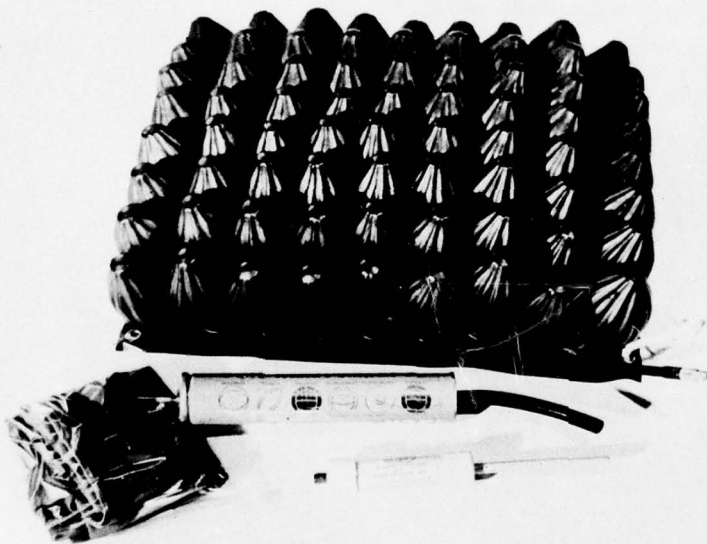


FIGURE 21.—RoHo Balloon Cushion.

inflated. The E-Z Patient Turning System is being evaluated at the VAH, Bronx, New York.

f. *Wheelchair Pad Movement Monitor.* The Wheelchair Pad Movement Monitor (Fig. 24), developed by the Southwest Research Institute, San Antonio, Texas, trains and/or reminds paralyzed wheelchair-confined persons to periodically shift their body weight during the day and thereby help prevent decubitus ulcers.



FIGURE 22.—Balloon elements shown attached to neoprene rubber base.



A battery-powered preset audible reminder sounds if the patient fails to shift his weight during a given period of time. The shifting resets the reminder circuitry via two electronic sensors (Fig. 25), secured beneath the patient's cushion. A digital display records the number of times these sensors are reset, so that the hospital staff can monitor the frequency with which the patient shifts his weight.

The Wheelchair Pad Movement Monitor will be evaluated at various VA Spinal Cord Injury Centers.

#### 5. Lifts and Transfer Aids

*LaCaron Lift Chair Model 76.* The LaCaron Lift Chair Model 76 (Fig. 26), produced by LaCaron Industries, Kenilworth, New Jersey was previously reported on in BPR 10-27. It is designed to enable persons who experience difficulties rising from chairs to do so, either independently or with attendants, easily and safely. The Model 76 Chair utilizes a counterbalance system that can be adjusted to individual needs. The chair was evaluated and is recommended for veteran beneficiaries.

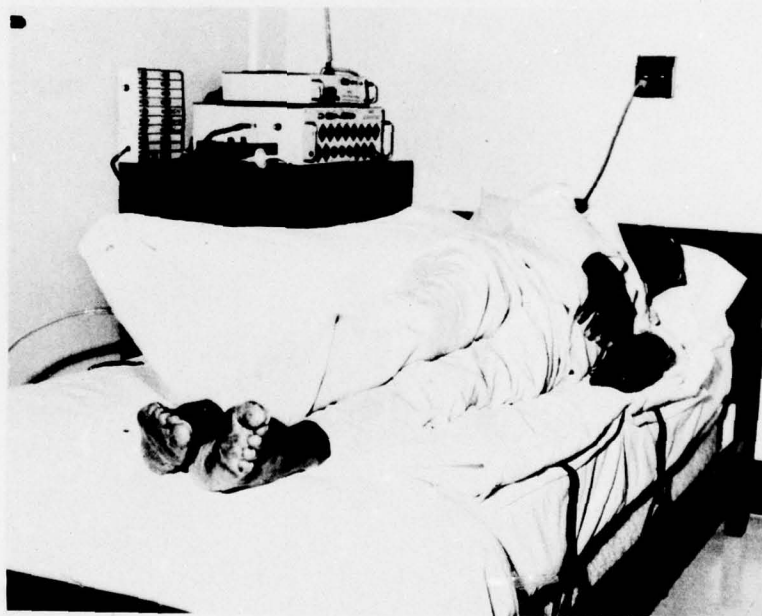


FIGURE 23.—E-Z Patient Turning System.

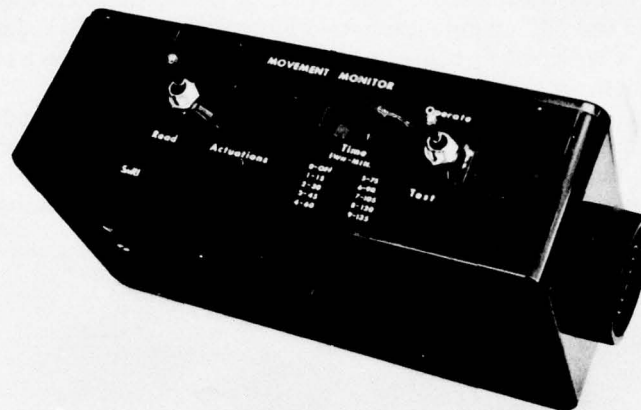


FIGURE 24.—Wheelchair Pad Movement Monitor.



FIGURE 25.—Wheelchair Pad Movement Monitor sensitivity switches.

6. *Driving Systems*

a. *E-Z Tilt-a-Board Loader*. The E-Z Tilt-a-Board Loader, Model 300 (Fig. 27 and 28), manufactured by Physical Aids, Inc., El Cajon, California, is designed to ease the loading of a wheelchair into a car trunk, a van, or station wagon cargo area.

A collapsed wheelchair is secured on the loader; with the loader leaning against the car bumper, the user bends down, grasps the handles of the loader, and lifts both loader and wheelchair, utilizing the trunk edge to support most of the weight. The loader is pushed into the trunk or cargo area on two casters.



FIGURE 26.—LaCaron Lift Chair Model 76.



One unit is being evaluated by a disabled veteran; additional candidates are being sought to evaluate this device.

b. *EZ-1 Wheelchair Carrier*. The EZ-1 Wheelchair Carrier (Fig. 29), manufactured by Wheelchair Carrier Corp., Phoenix, Arizona, is designed to facilitate wheelchair loading and unloading from an automotive trunk or cargo area by persons with limited strength.

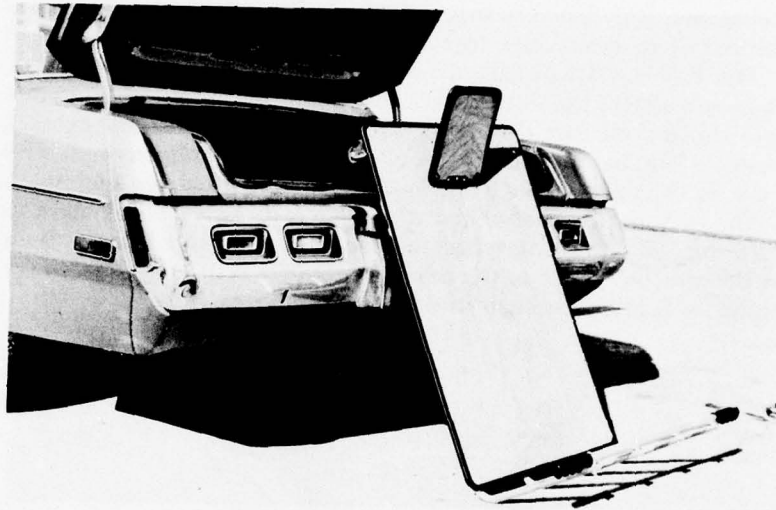


FIGURE 27.—Non-activated E-Z Tilt-a-Board Loader, above.



FIGURE 28.—Activated E-Z Tilt-a-Board Loader.

Aluminum chain-like links for leverage and flexibility designed to fit most types of automobiles that have been utilized to carry wheelchairs, are installed inside the trunk with a single screw (Fig. 30). The device is then positioned inside the trunk in such a way that the wheelchair is easily loaded without interfering with the spare tire.

Three units will be evaluated.

c. *Mann's E-Z Way Chair Lift.* Mann's E-Z Way Chair Lift (Fig. 31), commercially available from the M.E.W. Company, Tulsa, Oklahoma, is designed to load or unload a collapsed wheelchair into and out of an automotive trunk or cargo space.

The E-Z Way Chair Lift consists of a boom assembly and motor, and a wheelchair holding-bracket. The boom assembly comprises two cold rolled steel bars that are welded together: a 28-in. bar extends from a 12-in. bar at a 120 deg angle. An 80-in., 400-lb-strength steel cable is threaded through the steel bars, guided by two pulleys. A  $\frac{1}{4}$  hp, 12-V motor is attached to a 40:1 ratio swivel with ball bearings; this, in turn, is attached to a metal base mounted on the floor of the vehicle. A latch at the base of the boom is used to unlatch the boom for folding the chair into the trunk.



FIGURE 29.—EZ-1 Wheelchair Carrier.

One unit was submitted for evaluation; it has been installed in the driver-training sedan at the Castle Point, New York VA Hospital for clinical trials.

#### 7. Miscellaneous

a. *Bailey III Cushion Grip Tape.* Bailey III Cushion Grip Tape (Fig. 32 and 33), manufactured by Bailey III, Inc., Cheshire, Connecticut, is designed to provide a soft, comfortable, nonslip grip on such devices as mobility aids, eating utensils, and tools. It is readily available in retail hardware and sporting goods departments. Bailey III Cushion Grip Tape is composed of a rubbery plastic called Prolastic 75; it is said to be formulated to match the texture of the hands. Several rolls of the tape were evaluated at the Castle Point, New York VA Hospital. Although certain shortcomings exist in the use of the

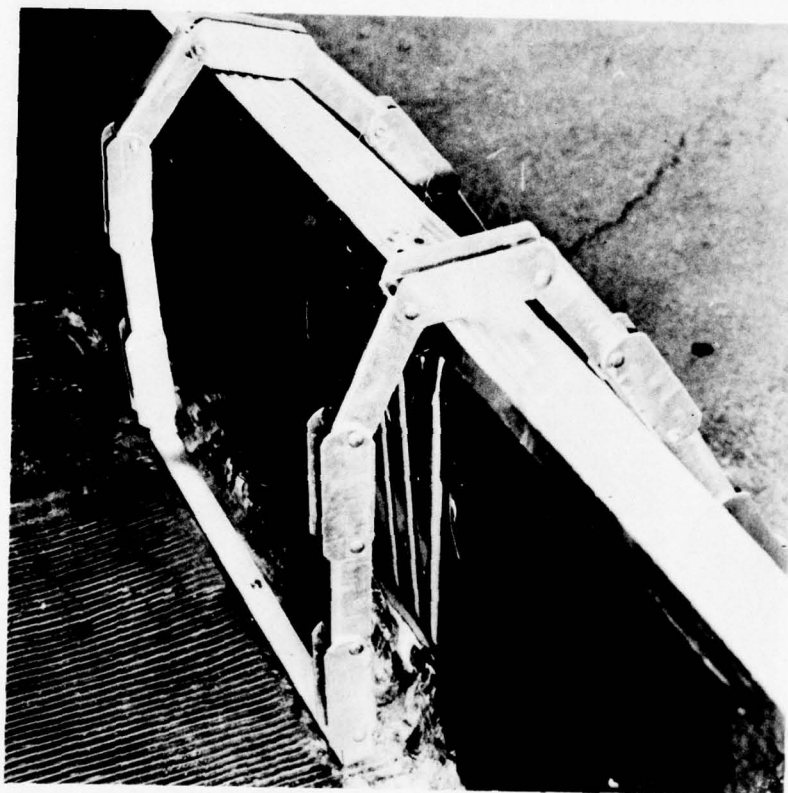


FIGURE 30.—Installing the EZ-1 Wheelchair Carrier.



tape, as revealed in the evaluation program, the tape is safe to use, and the potential applications vary widely.

b. *Winsford Feeder.* The Winsford Feeder (Fig. 34), originally identified as the Morewood Spoon Lifter, is distributed by Winsford Products, Inc., Pennington, New Jersey. It is a semi-automatic feeding device that allows a quadriplegic to feed himself independently: once the food has been placed on his plate and he has been properly positioned at the machine, the patient controls the operation of the device through head movements.

The Winsford Feeder, in its present form, was found to be useful by a small number of those veterans who used it during the evaluation. As presently designed, it is more useful to the newly injured and those with relatively mobile cervical spines. For these reasons, it is recommended that the device be made available, on prescription, to veteran beneficiaries who recognize its limitations. It has been further recommended that the manufacturer be urged to improve



FIGURE 31. Mann's E-Z Way Chair Lift.

the utility of the device, in accordance with a number of recommended improvements, so as to make it useful to a greater number of beneficiaries.

## II. COMPLIANCE TESTING

### A. Standards

A second draft of the standards for lower-limb prosthetics has been prepared (BPR 10-27), using the ASTM format. This document, now entitled *Standard Functional Requirements for Lower-Limb*



FIGURE 32.—Bailey III Cushion Grip Tape, applied to cane and tool handle.

FIGURE 33.—Application of Bailey III Cushion Grip Tape to a manually propelled wheelchair.



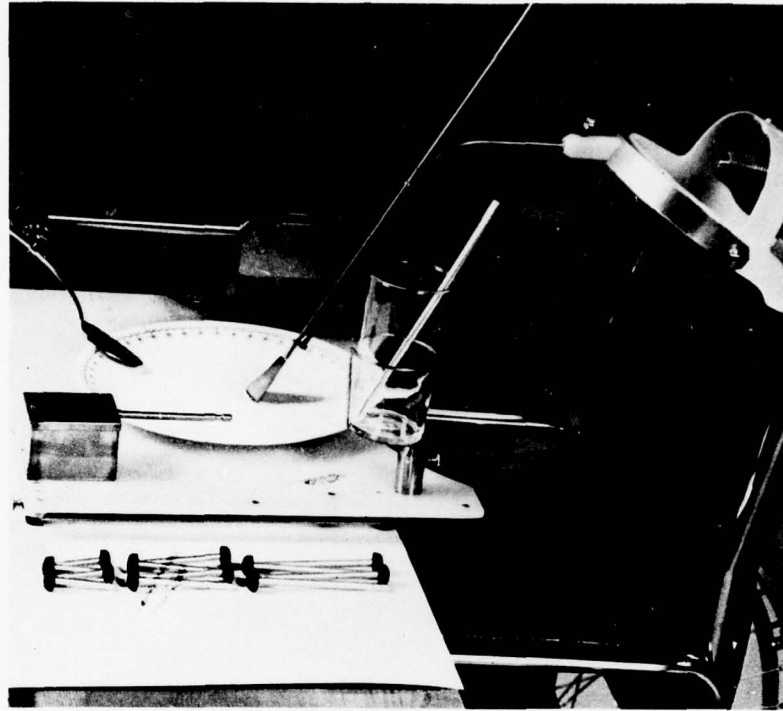


FIGURE 34.—Winsford Feeder.

*Prosthetic Assemblies and Components*, was presented at the International Conference on Standards for Lower-Limb Prostheses in Philadelphia, Pa., June 4-7, 1977. The participants concerned themselves with the section on static and dynamic testing since additional laboratory data on dynamic loads were presented at the conference by the BRADU representatives. An instrumented shank was used to collect these data.

The recommendations of the various panels have been added to a third draft of the standard now in preparation.

#### **B. Testing**

##### **1. Upper-Limb Components**

a. *Hosmer External Elbow Assembly*. Hosmer-Dorrance, Inc., Campbell, Calif. submitted an External Elbow Assembly for annual compliance testing. This assembly complied with the "Tentative



Specifications for Elbow, Artificial, External, Alternating for Above-Elbow Amputees."

b. *Sierra Voluntary-Closing Hand*. Hosmer-Dorrance submitted a Voluntary Closing Hand for annual compliance testing. This item complied with the "Tentative Specifications for Hand, Adult Size, Mechanical, Voluntary Opening for Upper-Limb Amputees."

2. *Lower-Limb Components*

a. *LAPOC Safety Knee*. The Labor Accident Prosthetics and Orthotics Center, Magoya, Japan, submitted a safety knee for testing and evaluation. The unit, a full-flexion, single-axis friction knee, is patterned after an Otto Bock modular design. An adjustable pneumatic damper, mounted within the shin tube, reduces terminal impact.

The unit was dynamically cycled to determine wear characteristics. It was flexed 120 deg at a rate of .7 Hz. Initially, the friction setting used throughout the test required 31.3 lbf · in (3.5 N · m) torque to flex the knee. The greatest amount of wear occurred during the first 50,000 cycles when the torque required dropped by 28 percent. The test was stopped at 397,000 cycles due to wear. At that time the torque required was 48 percent of the initial torque.

b. *Multiplex Mark II Above-Knee Prosthesis*. Fatigue testing of this assembly, initiated in February 1977, has four objectives:

1. To determine the fatigue life of the assembly by using the recommended loads contained in the draft standard.
2. To confirm that the recommended loads reflect the loads actually applied by a broad-based amputee population.
3. To determine whether variations in load-applications frequency affect the form of the load-feedback signals.
4. To discover the failure modes of the assembly; e.g., permanent deformation, brittle fracture, etc.

The assembly is mounted with the distal end up in the frame of the Instron biaxial servohydraulic testing machine. The linear actuator, acting through a test fixture, applies a compressive axial load and a combined AP-ML bending moment about the knee. The rotary actuator applies an axial torque. These loads, applied sinusoidally, are as follows: (i) Axial Load: 240 lb (1060 N); (ii) Bending Moment: 1065 lbf · in (120 N · m); and (iii) Axial Torque: 110 lbf · in (12.4 N · m).

The assembly has been cycled 2.2 million times at a frequency rate of 1 Hz, and then 1 million times at 5 Hz. The feedback signals

were not affected by the change in frequency. The test will continue until failure occurs.

### III. THE VAPC CLINIC TEAM

The statistical breakdown in Table 1 of the veterans treated by the VAPC Clinic Team during the first half of 1977 represents a typical case load. It is similar to those presented in previous BPR reports.

TABLE 1.—*Statistical Breakdown of Patient Disabilities January 1, 1977 to June 30, 1977*

Amputation		
Area of involvement	Specific level of involvement	Number of patients
Lower-limb unilateral	Below-Knee	153
	Above-Knee	117
	Transmalleolar (Syme's)	12
	Hip (Disarticulation)	7
	Partial Foot	3
	Mediotarsal (Chopart)	3
Lower-limb bilateral	Below-Knee	13
	Above-Knee/Below-Knee	12
	Above-Knee	7
	Transmalleolar (Syme's)	6
	Below-Knee/Transmalleolar (Syme's)	1
	Below-Knee/Mediotarsal (Chopart)	1
Upper-limb unilateral	Below-Elbow	14
	Above-Elbow	3
	Partial Hand	1
Upper-limb bilateral	Above-Elbow	1
	Below-Elbow	3
Lower-limb and Upper-limb	Above-Knee/Above Elbow	2
	Above-Knee/Shoulder (Disarticulation)	1
Triple	Above-Knee/Below-Knee/Below-Elbow	1
		(361 total)

# VAPC Research

Neuromuscular or Skeletal Impairment		
Area of involvement	Specific level of involvement	Number of patients
Lower-limb unilateral	Ankle-Foot	156
	Knee-Ankle-Foot	6
	Knee	3
Lower-limb bilateral	Ankle-Foot	1
	Knee-Ankle-Foot	13
Upper-limb unilateral	Arm-Elbow-Forearm; Wrist-Hand	7
Trunk	Lumbosacral spine	11
Lower-limb and Trunk	Ankle-Foot/Lumbosacral spine	1
Miscellaneous	Varied (Wheelchairs, shoes, etc.)	24
		(222 total)

Amputation and Neuromuscular or Skeletal Impairment		
Area of involvement	Specific level of involvement	Number of patients
Lower-limb bilateral	Below-Knee/Ankle-Foot	2
	Above-Knee/Ankle-Foot	4
		( 6 total)



## HIGHLIGHTS OF OTHER RESEARCH PROGRAMS

### PROSTHETICS

*Edited by*

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#### Research and Development in the Field of Artificial Limbs

Mauch Laboratories  
3035 Dryden Road  
Dayton, Ohio 45439  
Hans A. Mauch

#### Hydraulic Ankle Control System

The shakedown tests of the Hydraulic Ankle by the Research Center for Prosthetics and the VA Prosthetics Center, New York, are under way. Two amputees (one AK, one BK) were fitted and began wearing the experimental ankle at the end of May and the end of June, 1977, respectively. In both cases the initial amputee reactions were very favorable. Four more amputees (one bilateral AK/BK with the experimental ankle to be fitted on the BK side first and then on the AK side, and one hip disarticulation, a bilateral AK, and another BK) were recruited and will be fitted in due time.

The first test results (which relate mostly to noise) are being received and acted upon. Although the shortcomings seem minor, some tedious yet difficult work lies ahead, especially in two areas (piston rod neck and tip) where the hydraulic unit is attached to the shank. (The foot attachment appears to be working satisfactorily.) In both areas mentioned, compound motions (longitudinal plus rotatory plus tilting) occur at every step under several hundred pounds of pressure. These areas must be accommodated by suitably designed bearing surfaces to last for at least 1 year (approximately

one million cycles) without maintenance and without the need for non-solid lubricants. The present solutions work for a few weeks (depending on the activity and stress level); then noise develops as a result of wear.

The hydraulic unit itself, the development of which was a much more formidable problem, continues to work well. At the beginning of January 1977, the Dayton test amputee reported that he had been shoveling snow early in the morning at  $-20^{\circ}\text{C}$  ( $-5^{\circ}\text{F}$ ) without noticing any change in the unit's function. In April, he experienced difficulties in initiating flexion of his prosthesis when walking down a ramp with inclinations in excess of  $10^{\circ}$ . By design, the dorsiflexion stop, produced by the Hydraulic Ankle with the shank vertical and the foot pointing downward parallel with the incline, created too much alignment stability. Some degree of pole-vaulting was necessary on the part of the amputee to walk over the ball of the foot in this situation. As a remedy the forward travel of the ceramic control ball inside the hydraulic unit was limited to  $10^{\circ}$  by bending the front ends of the ball cage slightly inward. This had the effect of making the descent of ramps steeper than  $10^{\circ}$  much less precipitous because pole-vaulting was no longer necessary in both weightbearing and jack-knifing descent. This important improvement was adopted and incorporated in all test units.

At the end of April a program was started to improve the cosmesis of the transition between the lower end of the shank and the upper edge of the shaft of the foam foot (a thin, slender, reinforced upper edge). After a number of mold changes to this effect, a preliminary foot was made and put on the Dayton test amputee's prosthesis. It was found that the foam quality achieved was not satisfactory for this design: the foam at a density of  $32\text{ lb/f}^3$  was too stiff. A foam mixture resulting in a lighter density ( $25\text{ lb/f}^3$ ) did not fill the mold properly when mixed by hand in paper cups. It also produced too thick a skin and the pores of the foam were too large. It became clear that a small commercial type metering and mixing machine was needed in order to produce high quality foam feet for the ankles used in the shakedown testing program. The purchase of such a machine was approved by the VA in June, 1977; the machine was ordered and will be delivered in the middle of July 1977. It is hoped that a softer textured foam foot will also help to overcome "swishing" noises produced on occasion by friction between the upper edge of the foam foot and the outside of the lower shank.

**Hydraulic Knee Control System for Geriatric Amputees**

In February and March, 1977, the swing-control part of the Hydraulic Knee Control System for Geriatrics was completely redesigned. (Further tests with the previous design had revealed a lack of adaptability in obtaining various resistance profiles.) The new design still uses shaped recesses on the piston rod surface. However, the surrounding elements now contain vertical rows of suitably-spaced fluid exit holes (similar to the present design of the S-N-S system, but simpler). An added advantage of this new design, which will not add to the cost, is the fact that in the adjustment of the swing resistances for the various needs of the amputee, resistance increases and decreases are in proportion with the positioning of the adjustment elements. This is an improvement over the present S-N-S system where the resistance change is steeper at the high end of the adjustment range. In addition, several improvements were made in the design with the purpose of increasing its life expectancy and decreasing the work necessary in repairing it. These improvements will facilitate disassembly and reassembly.

**Voluntarily Actuated Swing and Stance Control System**

No reportable progress was made in the development of the Voluntarily Actuated Swing and Stance Control System due to higher priority work.

**Other Developments**

The adoption of the three-part bolt by the prosthetic supply industry is progressing satisfactorily.

The Ohio Willow Wood Co. has ordered 5,000 bolt assemblies from the All Metal Screw Product Co. They will soon have their wooden setups, also used for the S-N-S system, equipped with the new bolt. The Hosmer Corp. is also planning to incorporate the new bolt into their foam setup.

**Stump Stress Analysis  
Research Center for Prosthetics  
Veterans Administration  
252 Seventh Avenue  
New York, N.Y. 10001  
Leon Bennett, M.A.E.**

No progress report was submitted for this report period.



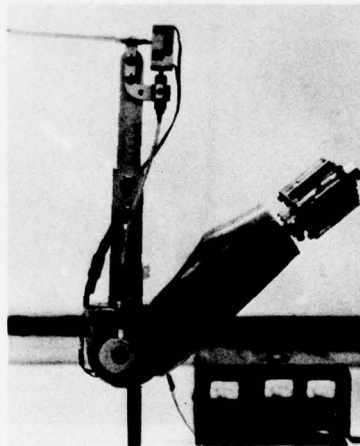
**Other VA Research Programs**

**Prosthetics Research  
Northwestern University, Prosthetics  
Research Laboratory  
Room 1441, 345 East Superior Street  
Chicago, Illinois 60611  
Robert G. Thompson, M.D., and Dudley S. Childress, Ph. D.**

**Design of a Powered Arm for Shoulder Disarticulation Amputees**

One of the many challenging problems of limb prosthetics is the design of a multifunctional artificial arm which can be controlled easily with some degree of subconscious control. This laboratory has continued the development of a laboratory prototype arm which uses Dr. David Simpson's concept of extended physiological proprioception (E.P.P.). Mechanically, this particular prototype arm is constructed around "unbeatable" position servomechanisms which have inputs from sterno-clavicular position.

An early prototype of the arm is shown in Figure 1. In this case only the VAPC elbow has been fitted with the feedback mechanism. The output position is fed back to the input lever through a "hydraulic link". This link also makes the system "unbeatable" by physically linking output and input. The error-detection scheme used (at this stage) is of the "on-off" (Bang-Bang) variety in an effort to keep the system simple.



**FIGURE 1. — Early prototype of a multifunctional artificial arm for the shoulder-disarticulation amputee.**

#### **Synergetic Hook Preliminary Evaluation**

The synergetic hook, developed in this laboratory, is being clinically evaluated on a small scale by the VA Prosthetics Center and the VA Research Center for Prosthetics, New York. This laboratory is providing repair for the field units. The study is yielding valuable design information, and the redesign of this prehension device has already begun. The system is being redesigned to permit easy fitting of the wrist disarticulation amputee, to allow reduced voltage and power, and to permit the use of exchangeable battery packs.

#### **Below-Elbow Myoelectric Fitting Techniques**

A new casting fixture has been developed for the Northwestern below-elbow socket (Fig. 2). The fixture maintains the arm in 45 deg of flexion and is adjustable for various arm lengths.

Alginate is used to take an undistorted cast of the limb. After the alginate has set, the limb is removed, the alginate supported, and a positive cast poured. Small pads are placed on the arm to mark the electrode locations. This casting technique, used in conjunction with the transparent Cellulose Acetate Butyrate (CAB) check sockets, has proved to be useful in the fabrication of below-elbow sockets for myoelectric prostheses.

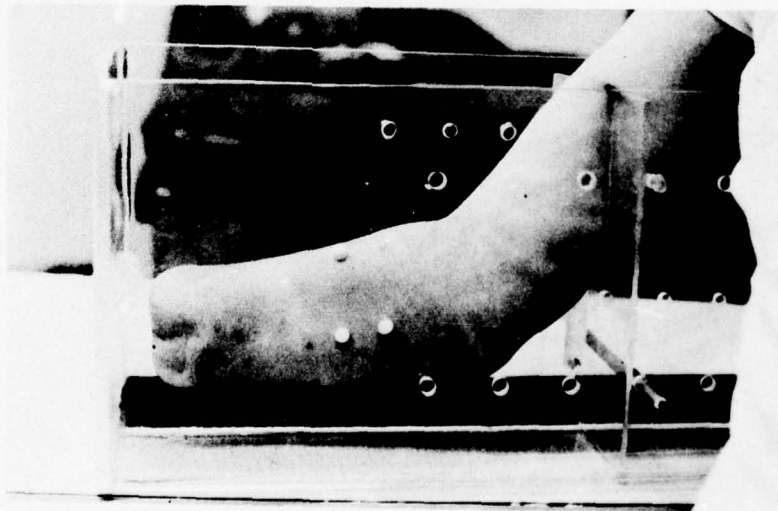


FIGURE 2. — A below-elbow myoelectric fitting technique.

**Lightweight Below-Knee Prostheses**

Three amputees (one bilateral) have been fitted with four of these prostheses. Work has been completed on improving cosmesis and on developing a fabrication technique for combining soft inserts with the polypropylene sockets. A bilateral amputee wearing the lightweight prostheses is shown in Figure 3. This illustrates that good cosmesis and lightweight construction can be combined. Figure 4 shows this subject removing her left prosthesis (note the soft Pelite insert).

The laboratory is planning to assist the Mid-West Chapter of AAOP with a workshop on lightweight prostheses during November 1977. It is hoped that this workshop will stimulate the use of this type of prosthesis in the private sector.



FIGURE 3. — Bilateral below-knee amputee wearing lightweight prostheses.





FIGURE 4. — Same subject with soft Pelite insert.

#### **Other VA Research Programs**

**Fundamental and Applied Research Related to the Design and Development of Upper-Limb Externally Powered Prostheses**  
Biotechnology Laboratory, 3116 Engineering 1  
School of Engineering and Applied Science  
University of California, Los Angeles  
Los Angeles, California 90024

John H. Lyman, Ph. D., Amos Freedy, Ph. D., Ronald Prior, Ph. D.,  
and Moshe Solomonow, Ph. D.

#### **Upper-Limb Prosthetic Research -- Control of an Artificial Limb with Several Degrees of Freedom of Motion**

Efforts toward a self-contained, microprocessor controlled, above-elbow prosthesis were continued during the 6-month period of January through June, 1977. System integration and upgrading were included in the work, whose aim is a clinical prosthesis.

The VA-UCLA prosthesis with three degrees of freedom of motion was improved by the inclusion of the new VAPC motors (now commercially available from the manufacturer, Fidelity Electronics, Inc.) for the elbow, wrist rotator, and hand. The prosthesis was tested and was interfaced to the development system (RCA COSMAC) for testing. UCLA miniature myoelectric amplifiers were also tested and interfaced to the development system.

The self-contained microprocessing system was completed and debugged and is now ready for software injection.

Interface circuitry, to input myoelectric signals (MES) and convert them to digital values for use by the computer, was constructed and debugged. All parts of the circuit were exercised. Amplification values were determined for the MES inputs. The input multiplexer and the analog-to-digital converter (ADC) were driven, using DC and MES inputs, to test them. Interface circuitry to output motor drive signals was also built and debugged.

The circuitry described here was connected to the RCA COSMAC micro-computer development system to allow the convenient writing and debugging of the Nearest Neighbor Classifier (NNC) system used in prosthesis control. The NNC system has been written and is in the process of being debugged and tested. The system uses the Nearest Neighbor Pattern Classification technique (distance calculations are made using a City Block Distance Algorithm). At the time of this report the system occupies approximately 1k of 8-bit computer memory, with room for some expansion if necessary.

Current work on this project includes:

- a. Subject testing experiments to debug final version of software and to calibrate the system before its injection into

the microprocessor.

- b. Construction of circuitry to allow transfer of the software from the development system to the microprocessor.
- c. Development of a belt-mounted power pack to energize the system.

#### **Prosthesis Sensory Feedback**

Work in the prosthesis sensory feedback project was continued in the completion of the investigation of the effects of pulse width and pulse time-delay effects on the electrotactile two-point discrimination of a sensory feedback display. It was found in subject testing that 100- $\mu$ s pulse-width results in superior discrimination, and allows larger numbers of channels to be included in the display.

It was also found that a pulse time-delay of 180 deg resulted in superior discrimination.

Current work on this project includes the investigation of electrotactile two-point discrimination hysteresis for ascending and descending thresholds, as additional necessary data for the specifications of the optimal electrotactile display.

#### **Effectiveness for Veteran Quadriplegics of Medical Manipulators, and Design Specifications for Improved Control**

Over the past 6 months, work on the evaluation of the effectiveness of medical manipulators has proceeded in two areas.

The first area has been the development of an effective evaluation protocol. The protocol has been designed to be sensitive to the extreme disability of the patient for whom the manipulators have been designed, and to the intimacy of interface which the patient's disability necessitates. The protocol has been designed in these three parts:

1. Bench Testing — Rigorous assessment of the safety and engineering aspects of the manipulator's function.
2. Performance Testing — Evaluation of training and performance of patients (associated with VA Hospital, Long Beach, California) in experimentally controlled tasks.
3. Clinical Testing — Assessment of the actual usefulness of the manipulator to patients, through monitoring of long-term use.

The second area of progress has been the implementation of the above protocol in the evaluation of the manipulators supplied through the VA Prosthetics Center, (VAPC), New York. The Biotechnology Laboratory has received two manipulators: the Rancho Los Amigos Remote Manipulator #12, and the General Teleoperator Telescoping Arm. The Telescoping Arm developed mechanical difficulty in the bench-testing phase of the evaluation, and conse-



quently is presently unsuitable for patient use. The Rancho Los Amigos Manipulator has proceeded through the safety and engineering evaluations, and is currently being used by four patients, representing a wide range of disabilities, in the performance-testing phase of our protocol.

**Design of Prosthetic and Orthotic Devices and  
Biomechanical Studies of Locomotion**

Biomechanics Laboratory

University of California, Berkeley

5144 Etcheverry Hall

Berkeley, California 94720

Charles W. Radcliffe, Don M. Cunningham, James M. Morris, M.D.,  
and Larry Lamoreux, Ph. D.

**Design of Lower-Limb Prosthetic and Orthotic Devices**

**1. *Four-Bar-Linkage Polycentric Pneumatic Knee***

A preshaped, flexible foam knee-cover has been designed, and a mold for its fabrication is being made with the assistance of the Navy Prosthetics Research Laboratory (NPRL), Oakland, Calif. Several elements of the knee unit have been revised in response to information obtained in clinical trials. These modified parts have been fabricated and assembled into a final revised prototype (Fig. 5). Complete engineering drawings of that prototype, along with the mold for the resilient knee fairing, will be delivered to the VA Prosthetics Center, New York, by the end of FY 1977. Extended clinical trials with commercially fabricated units are planned.

**2. *Six-Bar-Linkage Knee with Friction Swing-Control***

Clinical trials on three amputees at the Naval Hospital in Oakland have resulted in clinical acceptance on a functional basis, but the trials revealed inadequate strength and durability in the proximal bearings. One amputee fitted at VAPC, New York, has rejected the unit in favor of the OHC (Orthopaedic Hospital in Copenhagen) unit with hydraulic swing-control. (The VAPC trial also indicated the need for stronger bearings.) Partial revisions to two existing units have been made (Fig. 6) in order to increase bearing capacity and provide a positive extension stop. A thorough review of the design is underway, with the aim of obtaining even greater bearing capacity, along with improved appearance in the flexed position.

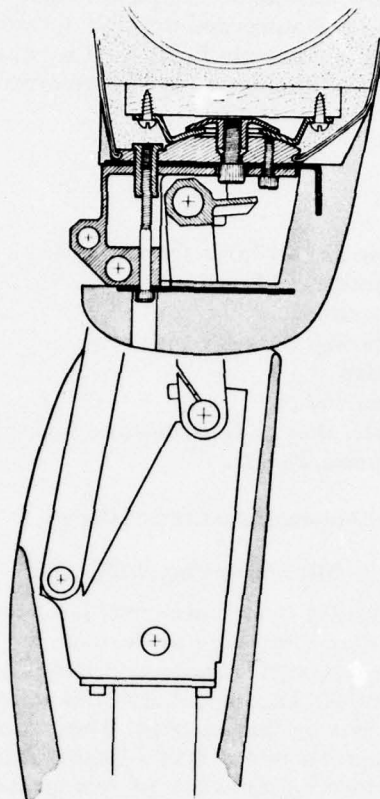


FIGURE 5. — The UC-BL four-bar-linkage polycentric knee unit, with spherical socket coupling and polyurethane foam knee-fairing system.

### 3. Friction-Stabilized Knee

There were three design goals for this knee unit: 1. friction knee-lock at heel contact, 2. release of knee friction prior to toe-off, and 3. adjustable friction swing-phase control from the same brake that provides knee lock. The second prototype (reported previously) satisfied the first two requirements, but not the third. That unit is shown schematically in Figure 7. Further experiments, with elastic

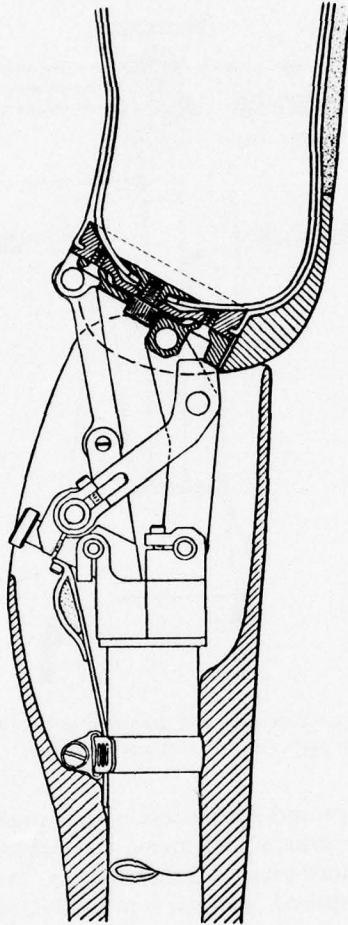


FIGURE 6. - The UC-BL six-bar-linkage knee disarticulation prosthesis with spherical socket coupling.



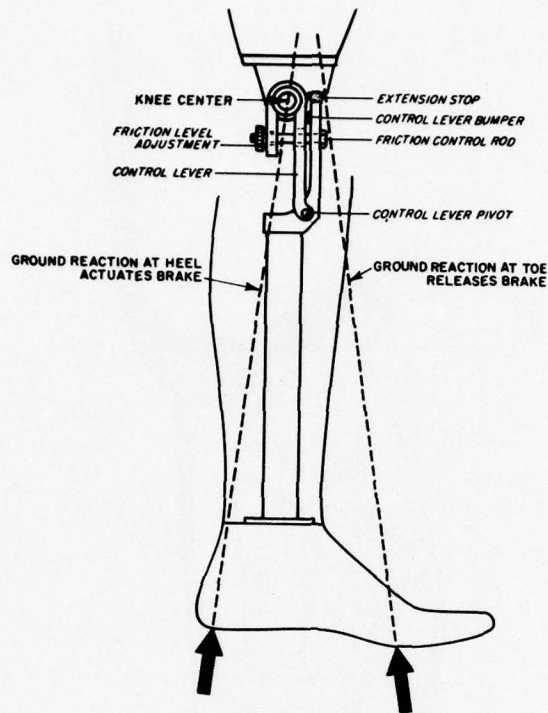


FIGURE 7. — Schematic representation of the UC-BL dual-action safety knee with heel lock and toe release.

knee extension straps and spring forces that push the control lever forward, resulted in satisfactory swing control without degradation of the desired stance-phase characteristics. A third prototype, incorporating the required changes, is being designed.

#### 4. Tube Coupling for Modular Prostheses

The internal, expanding, tubular-pylon couplings have undergone continued amputee and machine testing. Included in the tests were two couplings built into the new metal-keel SACH foot, three couplings for use with commercial SACH feet, and three couplings integrated into the design of linkage knee units. No problems have been encountered with loosening during use. Tests of a variety of materials have shown that a canvas-and-phenolic collar on an aluminum post with a brass locking-ring provides the best combination of sim-

#### Other VA Research Programs

ple manufacture, easy assembly into the tubing, and easy disassembly after long use. Two examples of the coupling are shown, one in Figure 8 and another in Figure 9. More widespread testing of this

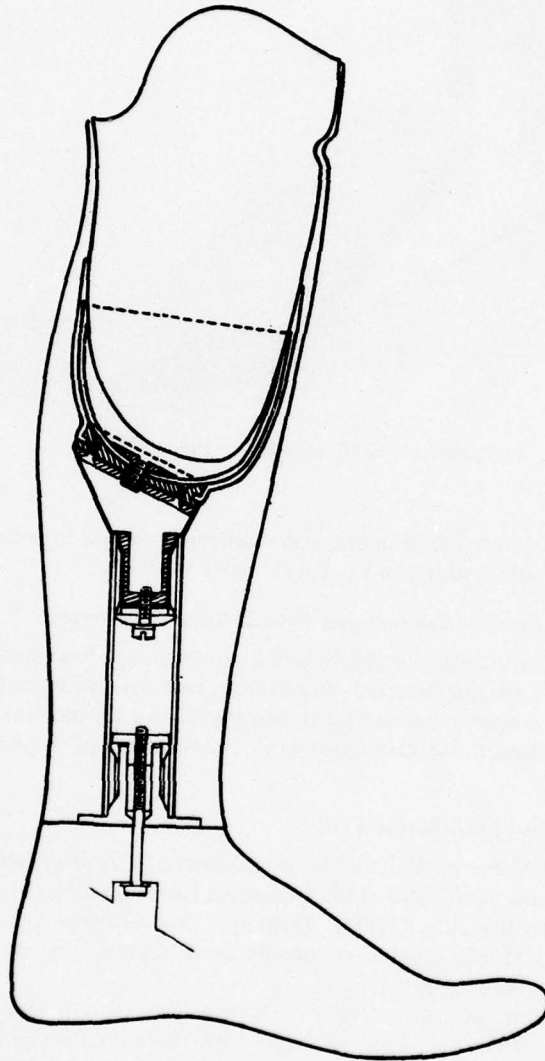


FIGURE 8. — The UC-BL modular pylon system for below-knee prosthesis, using the internal expanding tube coupling and spherical alignment coupling.

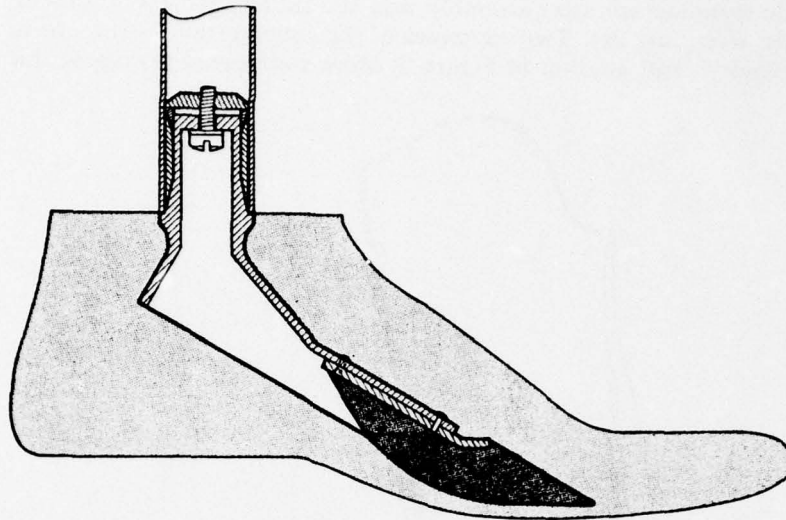


FIGURE 9. — The UC-BL metal-keel SACH foot.

coupling will occur during clinical evaluation of the four-bar-linkage polycentric knee, planned by VAPC for FY 1978.

#### *5. Modular Pylon Structure for Below-Knee Prostheses*

A pylon structure for the below-knee amputee has been designed to make use of the internal, expanding, tubular-pylon coupling and the spherical-alignment coupling used with the six-bar linkage knee. (Figure 8 shows the construction.) Fabrication of a prototype is under way.

#### *6. SACH Foot with Metal Keel*

Two additional models of the metal-keel SACH foot with integral pylon coupling and solid rubber cushion forefoot (Fig. 9) have been molded with the aid of NPRL, Oakland. One of these units was subjected to 100,000 cycles of accelerated testing on the Hosmer-Dorrance testing machine.

The second was worn by an AK amputee for three months. At the end of each test, the feet had worn through the molded foam under the forefoot to expose the solid rubber cushion. The aluminum keels and expanding pylon couplings showed no structural weakness. Functional characteristics of the foot are considered good by the amputee test subject, a long-time wearer of SACH feet.



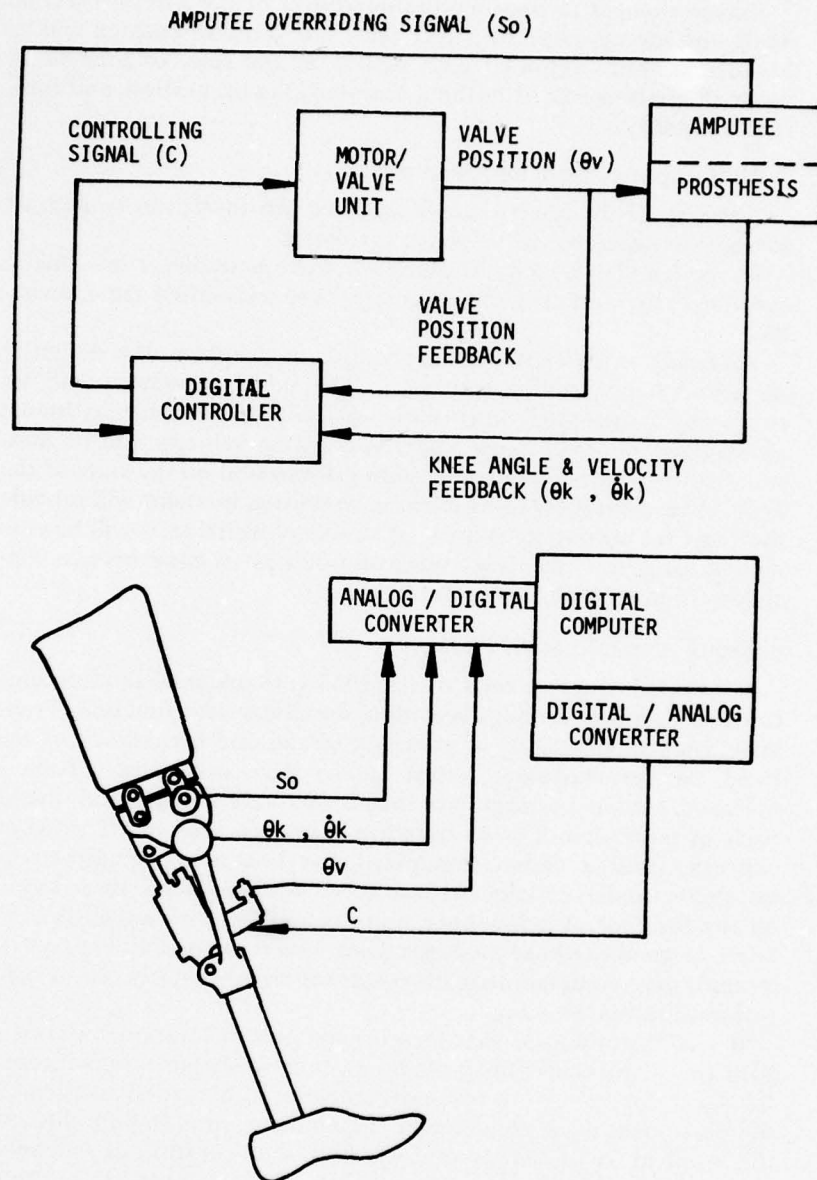


FIGURE 10. — Digital system for simulation of proposed analog/digital computer control of knee stability of above-knee prosthesis.

Design changes to improve the durability of the forefoot will be made and incorporated in future feet. The forefoot cushion will be broadened, and combined with belting in the sole, to provide an optimal combination of cushion forefoot, lateral motion, and forefoot durability.

#### *7. Multi-Input Control and Knee Stability*

Stability of the knee in an above-knee prosthesis can be defined in terms of knee angular velocity, as follows:

If the angular velocity is zero, the knee is stable; if less than a specified value, controllable; if greater than a specified value, unstable.

A project is under way to apply these concepts to the design of an active knee-stability controller. The initial prosthesis will incorporate a single-axis knee with remotely controllable hydraulic swing-phase control. Knee angle and angular velocity will be measured to provide the controller with information on the state of the knee. A measurement of hip flexion/extension moment will provide the basis for voluntary control of stability. Initial tests will be conducted using the laboratory minicomputer as an experimental controller. Figure 10 illustrates the system.

#### *8. Shank Axial Rotation Devices*

Continued amputee tests of the UC-BL shank axial-rotation unit confirm previous findings regarding durability and function. Problems, such as loosening of assembly screws and breakdown of the bond on the elastomer return spring, have occasionally been a nuisance, but the bearings have shown adequate strength and several trials of more than 2 years duration have been achieved. The major concern, from a design standpoint, has been with complaints of instability under certain circumstances due to lateral shear forces on the forefoot. A below-knee amputee walking over a slightly bent knee, or an above-knee amputee going up a ramp or walking on soft ground, may complain that the rotator suddenly rotates out of control until it hits the stop.

It was hypothesized that locating the axis of rotation concentric with the shank centerline provides an excessively large moment arm for shear forces on the forefoot, and that a relocation of the axis of rotation to equalize heel and toe moment arms should alleviate the problem. A prototype unit was built with rotation axis inclined to the shank centerline by 10 deg (Fig. 11). Amputee trials of that prosthesis indicate that the hypothesis was correct, and the problem has been corrected. This finding has direct implications for the design of more functional rotation units.

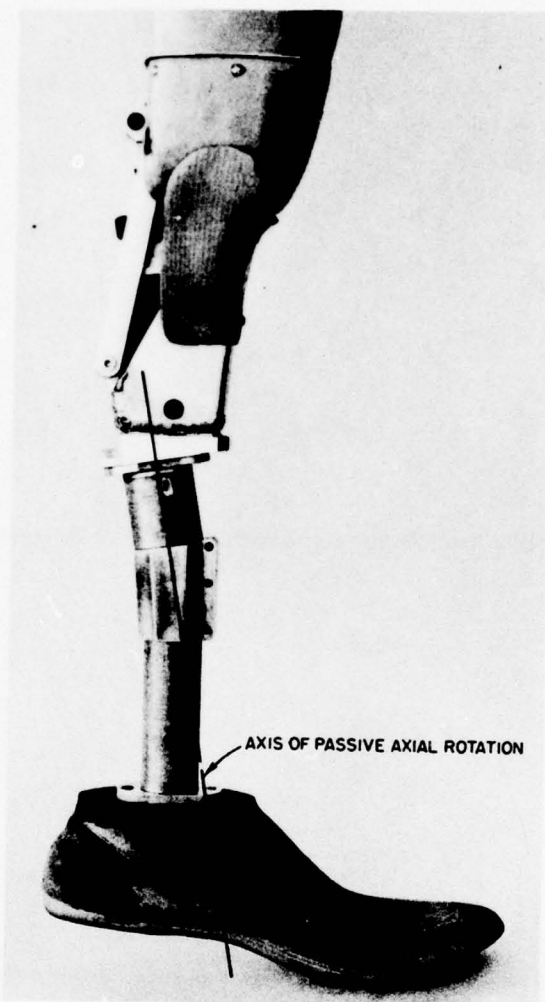


FIGURE 11. — Experimental installation of the UC-BL shank axial-rotation unit, with inclined axis of rotation designed to improve rotational stability when weight is borne on the forefoot.



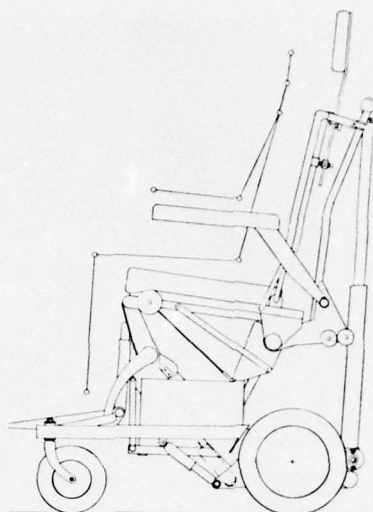


FIGURE 12a. — PRAHN II central-linkage wheelchair: high position.

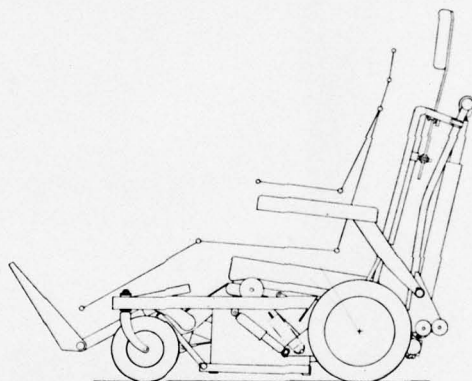


FIGURE 12b. — PRAHN II central-linkage wheelchair: low position.

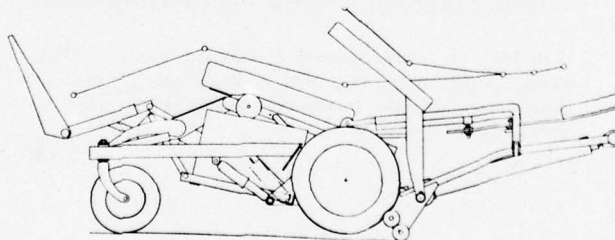


FIGURE 12c. — PRAHN II central-linkage wheelchair: reclined position.

The UC-BL shank axial-rotation unit has served its intended purpose as a medium for clinical assessment of the axial-rotation concept. It also has helped to stimulate increased industrial interest and activity in the development of production rotation units. In the future, the findings of this project will be applied to a comprehensive foot-design project rather than to the continued development of a separate rotation unit.

#### **Mobility Aids for the Physically Disabled**

##### **1. PRAHN Wheelchair**

The design of the PRAHN II wheelchair is virtually complete, and fabrication of the first of two prototypes is scheduled for completion by January 1978. Layout drawings of the chair in three positions are shown in Figure 12. This wheelchair has many improvements over PRAHN I, notably, larger battery capacity for range in excess of 20 miles over normal terrain, more powerful motors for improved hill climbing, a simplified linkage with lower-cost bearings, spring suspension, 2¾-in. ground clearance, electric failsafe emergency/parking brakes, and recline kinematics which simulate a hip pivot and keep the feet on the footrest. In addition, a curb climber for 8-in. curbs has been designed into the chair. As with PRAHN I, seat height is adjustable from 7 in. below to 6½ in. above normal seat height, with an articulated footrest which simulates a pivot at the knee as the feet "tuck in" during raising of the seat.

PRAHN II has a fixed 23-in. width, instead of the "narrowing" feature of PRAHN I.

One of the PRAHN II prototypes is scheduled for delivery to the VAPC for evaluation in October 1978.

##### **2. Spring Suspension Powering Unit**

The first prototype of this unit (Fig. 13) is still performing excellently after 15 months of daily use. A second prototype incorporating some changes will be delivered to the VAPC in March 1978.

##### **3. Urinal Bag Clamp**

A urinal bag clamp has been developed which allows a quadriplegic to empty his urinal bag by a 5-lb. pull on a leather thong. As can be seen in Figure 14, a spring-loaded roller squeezes closed

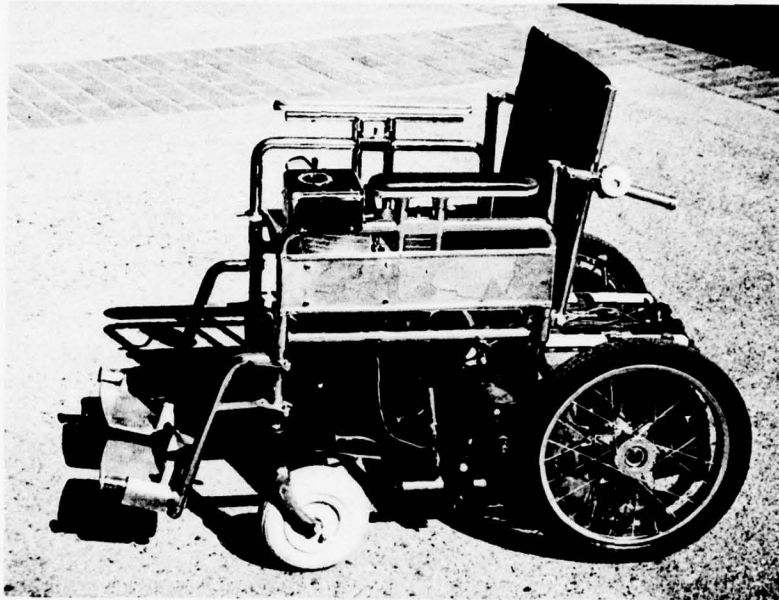


FIGURE 13a. — Spring-suspension powering unit: side view.

the rubber tube from the urinal bag, until the leather thong is pulled to empty the bag. All parts are external to the tube, so sterility is not a crucial problem. Local testing has been very successful, and five slightly simplified clamps are scheduled for delivery to the VAPC in September 1977 for evaluation.

**Immediate Postoperative Prostheses Research Study**  
**Prosthetics Research Study**  
Eklind Hall, Room 409  
1102 Columbia Street  
Seattle, Washington 98104  
Ernest Burgess, M.D.

**1. Controlled Environment Treatment**

The 3-year research protocol, using Controlled Environment Treatment techniques for the immediate postoperative management of below-knee amputations, has been concluded.<sup>a</sup> The system has

<sup>a</sup> See article in this issue.



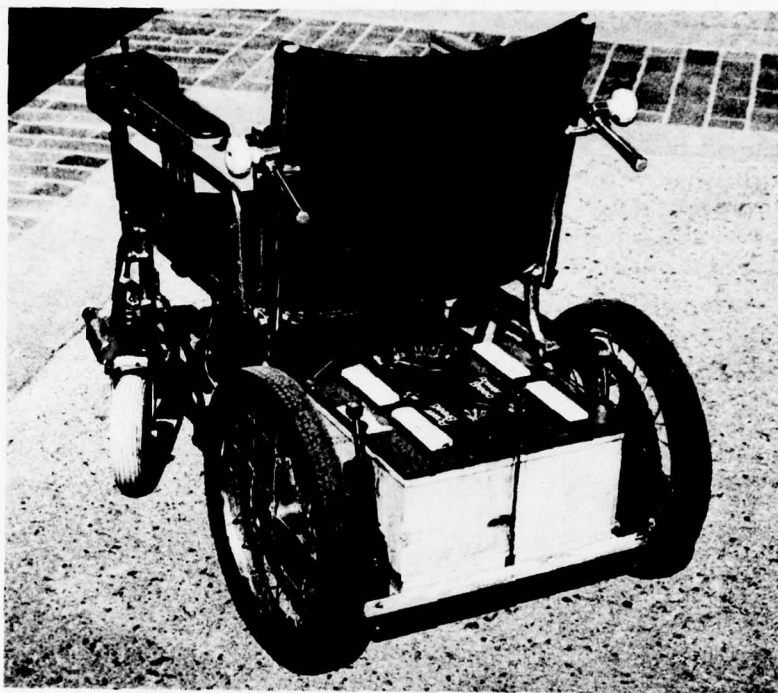


FIGURE 13b. — Spring-suspension powering unit: rear-quarter view.

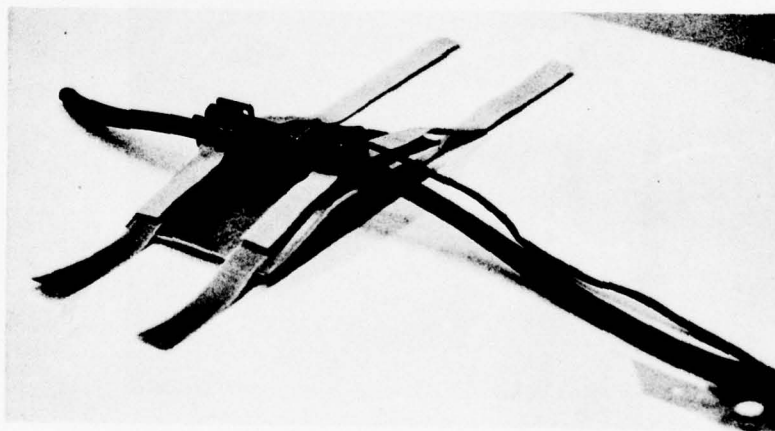


FIGURE 14. — Second prototype of urinal bag clamp.

now been incorporated into our regular postoperative treatment program where experience indicates its advantages. Prosthetics Research Study Group (PRS) has developed and produced a simplified mechanical unit incorporating basic CET principles (Fig. 15). Clinical applications of the CET include fresh trauma, acute and chronic limb edema states, pain abatement, alteration of peripheral circulation in ischemic diseases including stasis ulcers and gangrene-threatened digits, fresh limb surgery and trauma (exclusive of traumatic amputations), decubiti and related pressure-induced lesions. The smaller portable unit allows home use of CET.

Incorporation of thermal and electrical modalities in the CET system is being tried in the management of acute trauma, particularly severe ankle sprains, etc. We are also exploring the use of this

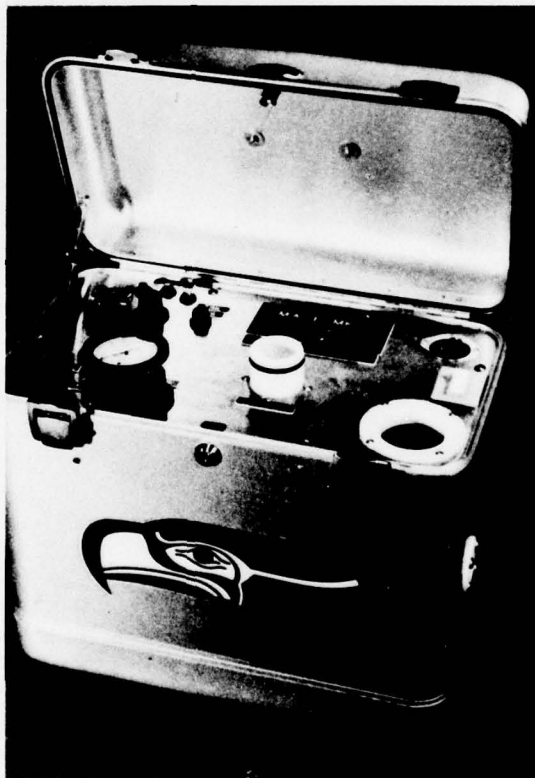


FIGURE 15. — PRS-designed MACE (Modulated Air Controlled Environment) unit for non-sterile pressure regimes.

means of external tissue environment control in Raynaud's disease, Buerger's disease, and similar vaso-spastic states.

A small model of the CET system has been made by James Moore of PRS and is being used by Dr. F. A. Matsen, III, and associates to study experimentally the effects of pressure on edema, skin and muscle circulation, and nerve conduction times. The rabbit is the experimental model.

#### **2. Studies of Skin Blood Flow as Related to Amputation Level**

Our initial experience using Xenon<sup>133</sup> to assay dynamic skin blood flow, pre- and post-amputation, in patients with ischemia has been accepted for publication by Surgery, Gynecology and Obstetrics. This work is continuing, in the hope that it can be made clinically useful generally. Further experimental inquiry into skin circulation is being initiated in cooperation with Dr. A. J. Holloway, using the non-invasive laser-doppler system which he has developed. This innocuous, non-invasive assay will also be used pre- and post-amputation in the study of ischemic limbs.

#### **3. Physiological Suspension**

Our ongoing work continues in the physiological suspension of the below-knee prosthesis using residual limb muscle activity.<sup>b</sup> We anticipate continuing observations in this area, with specific direction toward prosthetic design changes for incorporating interface contours to further improve physiological limb suspension. The functional benefit derived from this approach to physical interface relationships can have far-reaching effects on amputation surgery, physical rehabilitation of the residual limb, and prosthetics design.

#### **4. Extra-ambulatory Function for the Lower-Limb Amputee**

Working in cooperation with Drs. D. Miller and R. Hutton, Department of Physical Education, University of Washington, we have been objectively evaluating physical skills primarily related to sports and recreation, and how they can be improved in the lower-limb amputee, primarily the younger patient. Recently, separate funding from the Veterans Administration has been provided Drs. Miller and Hutton, who will continue and extend these studies under PRS supervision.

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<sup>b</sup> See article in this issue.



**5. Functional Capabilities of Lower-Limb Amputees**

Bernice Kegel, R.P.T., and Margaret Carpenter, of our rehabilitation staff, have completed and reported an extensive functional capabilities survey on a statistically significant controlled amputee population during a 10 year follow-up. An extension of these studies is underway, monitoring social adjustment and lifestyle in depth.

**6. Revision Amputation**

There is a real need for definition of the principles of revision surgery, especially in the lower limb where the primary amputation was performed for ischemia. The past 10 years has seen a dramatic lowering of the level of primary amputation for peripheral vascular disease. Functional and economic benefits have been great. No modern guidelines exist to define the technique and levels for revision when this becomes necessary. Drs. E. M. Burgess and L. Pedegana are now reviewing 100 consecutive lower-limb amputations for the establishment of guidelines and anticipated results.

**7. Amputee Service**

The amputee service at the Seattle Veterans Administration Hospital continues active with a steady increase in the number of surgeries performed and rehabilitation problems referred.

**Below-Knee Amputation with Immediate  
Postoperative Fitting of Prosthesis  
VA Hospital  
Tucson, Arizona 85723  
Wesley S. Moore, M.D.**

Dr. Moore has recently moved this project from the VA Hospital, San Francisco, to the VA Hospital, Tucson, Arizona, in conjunction with his acceptance of a new position as Professor and Head, Section of Vascular Surgery, University of Arizona. He plans to continue the randomized controlled study, comparing immediate postoperative fitting of prosthesis with use of the controlled environment chamber, once appropriate arrangements are made in his new location.

**Interdisciplinary Development and Evaluation of  
Externally Powered Upper-Limb Prostheses and  
Orthoses**

**Applied Physics Laboratory  
The Johns Hopkins University  
8621 Georgia Avenue  
Silver Spring, Maryland 20910  
Woodrow Seamone and Gerhard Schmeisser, Jr., M.D.**

During the first half of 1977, research at Johns Hopkins continued to be focused on the completion of a computer-aided medical manipulator worktable system. In addition, clinical evaluation was continued on a manipulator/worktable with a quadriplegic volunteer who has now accumulated approximately 18 months of experience with this system.

**Computer-Aided Powered Medical Manipulator**

During FY 77, an advanced powered medical manipulator was designed with microprocessor control. The basic design approach for the system was described in BPR 10-27. Briefly, this system uses the microprocessor to effect smooth manual control, and more importantly, it allows the use of stored programs to assist in tasks which primarily involve deterministic trajectories.

One important change in this model compared with previous models is the incorporation of an integral microswitch on the chin transducer, for mode command. Slight forward motion of the chin against this microswitch selects the mode to be operated. Downward motion of the chin controls proportional motion. Thus, total control of the manipulator is achieved by chin motion, with excellent decoupling between the two control modes. Previous models used a separate microswitch located elsewhere (near a suitable muscle) or an eyeglass-mounted sensor responding to teeth-click inputs, for mode selection.

With the addition of the microprocessor, 12 programs have been placed in the system memory. Capability for a number of additional programs remains: Each prestored program is assigned a number from 1 to 20. When the operator desires to select (call up) a specific program, he or she presses the microswitch to stop the selection scanner at the moment PROGRAM is illuminated on the sequence display panel. After PROGRAM has been selected, the sequence display counts by tens and then by ones to enable the operator to designate the two-digit number which has been assigned to the desired program. The basic computer software was configured to simplify inputs required to generate these prestored

programs. For each step of the program, only the selected mode and end-point need be entered.

The software routine instructions provide for appropriate voltages for acceleration ramp up (linear increase), velocity limit, and ramp down, to insure smooth motion. Manual-mode control and/or PAUSE may be written into the program at any place in the sequence of motions. During the program generation phase, these programs are entered into the read/write memory, checked for accuracy of positioning, and then transferred to a programmable read-only memory (PROM) chip.

To illustrate the versatility of this concept, a description of some of the programs which have been implemented follows:

#### *1. Telephone Programs*

The general layout of the latest manipulator/worktable arrangement is shown in Figure 16. A Trimline Touch-tone wall phone is placed on a mounting bracket on the right side of the worktable. A small bracket is clamped to the hand set. The first of the telephone prestored programs directs the manipulator to go from its designated standby position to the phone location, pick up the phone and move it to the correct position adjacent to the user's head. The phone remains in this position until a single pulse is activated via the chin microswitch to return the phone to its holder. A second program is selected in the event the user would like to place a call. In this instance the manipulator brings the phone into a position suitable for "dialing" with the mouthstick. After the dialing of the number, the manipulator brings the phone to the ear and, after the call has been completed, returns the handset to the stand as before. In the event the user would like to stop motions during program mode, he need only activate one pulse with the microswitch to stop the motion and cause the manipulator to revert to manual control.

#### *2. Self-Feeding Programs*

Two self-feeding programs have been investigated. One allows manual control near the plate for food management with the spoon. It automatically transcends into an automatic motion, once the spoon is lifted past a certain point, to bring food to the user's mouth. The system pauses then, until the user takes a bite and activates the chin microswitch to automatically return the spoon to the vicinity of the plate. This cycle is repeated at the control of the user.

A second program provides for eating soup from a bowl. In this instance, the spoon will automatically go from the plate to the



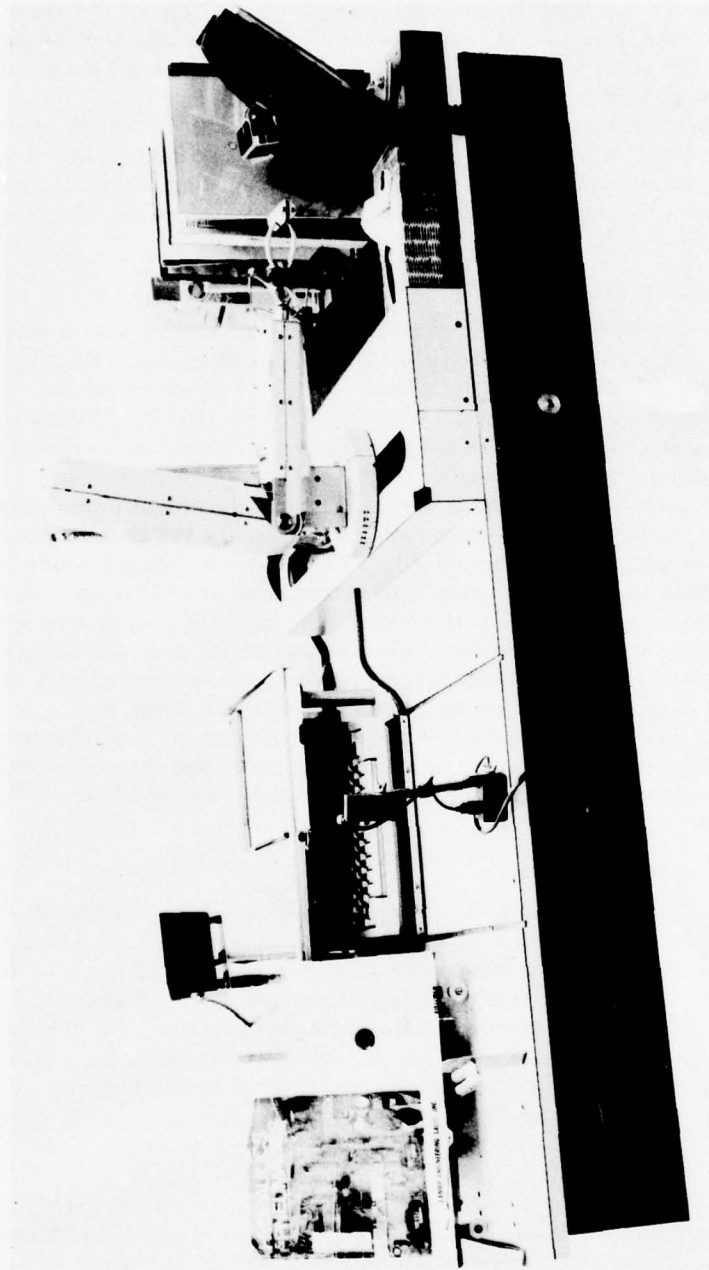


FIGURE 16. — Computer-aided powered medical manipulator worktable system: the latest table layout.

soup bowl, dip into the soup bowl, wipe the bottom of the spoon against the rim of the bowl to minimize dripping, and finally bring the soup to the user's mouth. A bowl of hot soup can be consumed in approximately 5 minutes.

Either self-feeding program requires minimal effort on the part of the user, and eating a complete meal may be accomplished in 15 to 25 minutes. During self-feeding, a cupholder with drinking straw is provided within reaching distance, to allow liquids to be taken during the meal.

### 3. *Book/Magazine Programs*

The book/magazine storage rack and the reading stand must each accommodate a variety of sizes of reading materials. This system as designed will handle small hardcover or paperback books, slick magazines measuring 21.6 cm by 27.9 cm (8½ by 11 inches), and stapled memoranda. Reading materials weighing up to .567 kg (1¼ pounds) may be managed.

The prestored program is written to move the arm automatically to the vicinity of the storage rack and adjust the hook to the open position facing the unbound edges of the book. Manual mode is then used to locate and grasp a particular book and lift it vertically. The program continues at this point in an automatic mode to place the book in its final reading position on the reading stand. Pages are turned with a mouthstick (and prevented from turning back by a wire finger mounted on the reading stand). The book may be returned to its original position in the storage rack by a similar prestored program which contains both automatic and manual modes to accommodate the shapes and sizes of books which must be handled.

### 4. *Typewriter program*

This program brings the typewriter out of its storage position and inserts a sheet of paper ready for typing. The program is fully automatic and is used in conjunction with use of the mouthstick to activate the typewriter carriage-paper roller to advance the paper. (A pause is provided in the prestored program to allow this to happen smoothly.) Upon completion of typing on a given sheet of paper, the vacuum fingers on the terminal device may be used to remove the sheet and place it elsewhere for storage.

### 5. *Kleenex program*

One possible task for the manipulator is to grasp a tissue such as a Kleenex and hold it near the patient's face. A prestored program has been written to accomplish this task: it automatically brings

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the tissue to the user's face. He may then manually maneuver it into a desired position. The program ends by automatically depositing the tissue into a waste basket.

These programs were written to allow evaluation of the concept of an appropriate mix of manual and automatic control. Forthcoming clinical evaluation will provide a realistic assessment of the practicality of this approach. As of the end of this reporting period (July 1, 1977) the computer-aided manipulator was in its final stages of the fabrication of the worktable components, and preparation of prestored programs. The system is expected to be ready for clinical tests by mid-September 1977.

#### **Continuation of Clinical Evaluation of the Manipulator**

As of July 1, 1977, the manipulator/worktable module has undergone approximately 18 months of evaluation by a quadriplegic, with lesser evaluation of a previous model by an earlier user.

The present user typically uses the equipment approximately 3-5 hours per day, to carry out vocationally related tasks such as handling reading materials, the telephone, and the typewriter. Because that model did not incorporate the microprocessor controller, functions such as self-feeding were not deemed practical for long-term evaluation. However, demonstrations were made of the self-feeding mode, to verify that the geometry and basic mechanics of motion allow this function to be successfully carried out.

Various methods of inputting the system were investigated. The original system utilized a microswitch placed near the user's arm to provide the pulse input for sequence command. Upon selection of a desired function, proportional control was achieved by depressing the chin lever. As an alternative to the microswitch, a special pair of eyeglasses was fitted with a small accelerometer for sensing "teethclicks." The user preferred the ease of using the eyeglass system over the microswitch, but did not like the idea of wearing eyeglasses for long periods of time. That led to the concept of incorporating the microswitch as an integral part of the chin transducer, which has been accomplished in the new computer-aided model. It will be clinically evaluated by the same user during the Fall of 1977.

An alternative to the microswitch is a pneumatic sensor integral with the chin transducer: for this, a series of holes was drilled in the chin transducer support tube to allow breath puffs to be detected by a thermistor bridge air-velocity transducer. (This concept provides a good pulse signal but is highly directional and control is more difficult to carry out in a consistent manner: the concept



was demonstrated in the laboratory but did not seem practical for clinical use.)

The experimental manipulator/worktable system was scheduled for removal from the current user during August, to be updated with the computer-aided manipulator. Clinical tests are expected to be resumed in mid-September 1977.

**Development of Refined Fitting Procedures for Lower-Limb  
Prostheses — Case Studies of Applied Research in Orthotics  
and Prosthetics, A Final Report**

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**Introduction**

This project was designed as a research approach in the management of patients with limb loss and/or dysfunction of the lower limb who present difficult problems in prosthetic substitution or in orthotic control. The investigators realized that there exists a significant patient population who, due either to the severity or the multiplicity of their handicaps, cannot be adequately managed by "standard" prosthetic and orthotic approaches. It is also realized that although this total number is significant, the number of such patients with identical functional loss or identical complicating factors is small. It is difficult, therefore, to group these patients into categories of disability which would provide common bases for prosthetic or orthotic design.

In the past it has been the usual research practice to design a particular device to solve a problem which is common to a large number of patients. Even that problem, with variations, may not be well managed by the device, and patients who have relatively rare problems are generally not adequately managed by any standard available appliance. These patients are best managed by *individual* solutions to their problems: devices should be designed specifically to meet the needs of the individual patient. This is the opposite of attempting to fit the patient into pre-existing standard hardware.

To be effective, the individual approach requires careful and systematic clinical analysis by a team of professionals, including physicians, engineers, prosthetists, orthotists, and therapists.

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Evaluation is followed by design and re-design of appropriate devices until the optimum solution to the biomechanical deficits has been achieved. Confirmation that this has been achieved requires careful study and followup including analysis of gait, an estimate of comfort, cosmesis, and function by both the patient and the clinic team, and determination of device durability.

The primary research aim of this project has been to demonstrate the feasibility of a careful, analytical approach to patients with difficult problems of the lower limb by a multi-disciplinary team, and the translation of information so gained to a satisfactory prosthetic or orthotic solution.

At this time the project is expanding, and the techniques developed will be incorporated into the more "routine" patient care of the clinical program which will continue the handling of the difficult cases. The new program will include upper-limb and spinal cases as well as lower-limb cases, but otherwise the technique of patient care and evaluation will be similar to that described.

#### Method

A clinic team met monthly at Jackson Memorial Hospital for special problems of the lower limb. In attendance at the clinic were two orthopedic surgeons, an engineer, a physical therapist, a prosthetist, an orthotist, and a secretary-photographer. Patients were referred to the clinic from a number of sources: these included the Veterans Administration Hospital, Jackson Memorial Hospital Amputee Clinic, the Rehabilitation Center at Jackson Memorial, outside physicians, prosthetists, orthotists, and professionals from other Veterans Administration Hospitals. A careful physical examination and functional evaluation by the entire team preceded the decision on whether to include a patient in the case study program. If a patient was included in the program, the team again collaborated to record a thorough, detailed physical examination, history, technical analysis, device analysis, and photographic record. The patient also evaluated his existing device and its function. A file was made on each patient, including the following records and materials:

1. General information sheet;
2. Medical dictation;
3. Technical analysis form for orthotics;
4. Analysis forms for prosthetics;
5. Device evaluation form;
6. Gait analysis form; and
7. Photographic envelope.

Following the initial evaluation of each selected patient, the clinic team collaborated to determine and define the best possible prosthetic or orthotic solution to the patient's problem. Patients were subsequently seen, measured and casted, and then fitted with the device prior to the next clinic. At the next clinic visit, if the device appeared to solve the problem adequately, (in the view of the patient as well as the clinic team) arrangements were made for further device evaluation by gait analysis studies, and subsequently by subjective and objective evaluation by both the patient and the team. If (at this point) the device was deemed unsatisfactory, a new solution was proposed and the process repeated.

Followup on each patient was for a minimum of 1 year after fitting of the final device and completion of training. Device evaluation by the patient and clinic team, and gait analysis, were performed at least every 6 months for original devices, subsequent devices, and without any device at all when feasible. A running photographic record was maintained.

Patients with two types of needs were included in the program:

1. Patients for whom no conventional orthotic or prosthetic device has been adequate for solution of the problem.
2. Patients for whom available conventional treatment proved sub-optimal in function, comfort and cosmesis. This group included patients with relatively severe disability, although not uncommon problems, who could be managed in a way superior to the conventional solution.

Examples of the first group included the multiple amputee, the patient with severe paralysis, the patient with a combination of paralysis and amputation, and the patient with a complicating condition such as contractures, spasticity, and skin breakdown.

Examples of the second group are those cases of paralysis and/or amputation for whom conventional solutions are sub-optimal because of excessive energy expenditure, functional handicap, or lack of comfort or cosmesis. Included were cases of polio, hemiplegia, unilateral below-knee amputees, or above-knee amputees with complicating problems.

#### **Patient Population**

Thirty-three patients have been included in this study. At the close of the study (as a research project) 25 out of 33 patients were being followed and these will continue into the clinical program. The 33 cases included 23 orthotic patients and 13 prosthetic patients. Three patients had both orthotic and prosthetic problems.



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*Of the orthotic patients*, 11 had poliomyelitis, 3 hemophilia, 1 Charcot-Marie Tooth disease, 1 spina bifida, 1 tubercular meningitis, 3 trauma with secondary problems, 2 cerebral vascular accidents (CVA), 1 diabetes, and 1 Guillain-Barré syndrome. Paralysis was the major problem in 18 patients with secondary problems of spasticity in 1 case, severe skeletal deformity in 1 case, and balance dysfunction in 1. Joint deformity was the major problem in 6 cases, with secondary problems of pain in all 6, plus skin breakdown in 2, infection in 1, and limited range of motion in 3.

*Of the prosthetic cases*, 17 had multiple-limb involvement. Two had bilateral below-knee amputations, 3 had bilateral above-knee amputations, 2 had upper-limb involvement, 2 had bilateral hip disarticulations, 2 had unilateral Symes amputations, 2 had unilateral below-knee amputations, 1 had unilateral above-knee amputation, and 4 had skin problems. Secondary complications in the prosthetic cases included: 1 above-knee amputation with removal of the ischial tuberosity, 4 with skin breakdown problems, 1 with phantom pain, 2 with associated lower-limb paralysis, 1 with paraplegia, 2 with contractures, and 2 with extremely short residual limbs.



FIGURE 17. — Example of a pre-tibial shell design in thermoplastics, for control of the knee joint without the need of elaborate knee mechanism.

#### Orthotic Approach

In general the approach to orthotic paralytic problems in the lower limb included the use of custom-molded thermoplastic shells to which metallic joints were attached for the knee where necessary. All ankle mechanisms used were flexible polypropylene posterior joints, molded into the foot and calf sections as one piece.

Knee-control mechanisms included designs such as pretibial shells molded of polypropylene, inverted Klenzak extension joints for variable extension control, and locked hinge joints with short up-rights laminated in the polypropylene shells (Fig. 17, 18, 19).

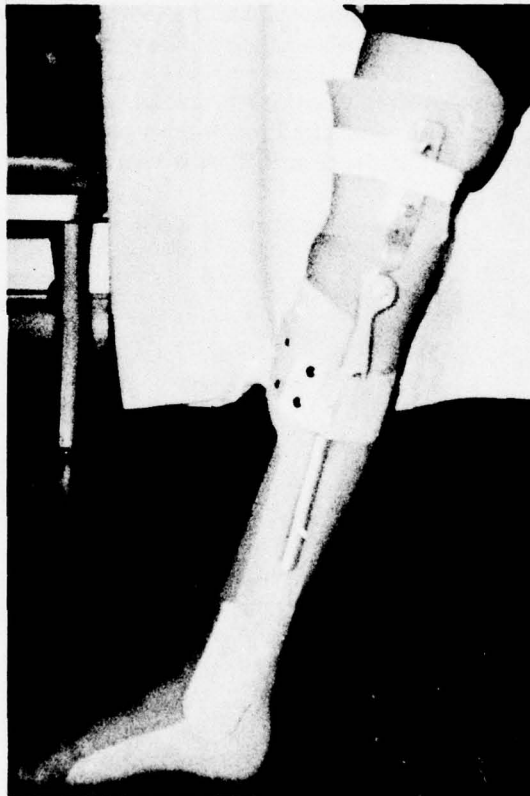


FIGURE 18. — An example of the typical use of thermoplastics with adjustable stop knee mechanisms and free knee flexion.



FIGURE 19. — An example of the use of thermoplastics with locked knee mechanisms.

Two new hardware component designs were attempted. The first requires further development. The idea was to provide good medial-lateral stability and a strong extension stop without using double uprights. A wide hinged posterior upright served this purpose but the collapsing links which provided the required length reduction of the upright in flexion did not operate consistently on patients when they flexed to sit. A linkage system needs to be developed to force the proper coordination of links during flexion (Fig. 20).

The second new knee component was designed to damp rapid knee motions and protect trauma. A knee cage with polypropylene shells had attached flexible metal cables across the joint to give resistance to knee motion. Although this device did not give a velocity-dependant resistance (for true damping) it did accomplish the required task and was much simpler to fabricate. Preliminary results appear promising (Fig. 21).



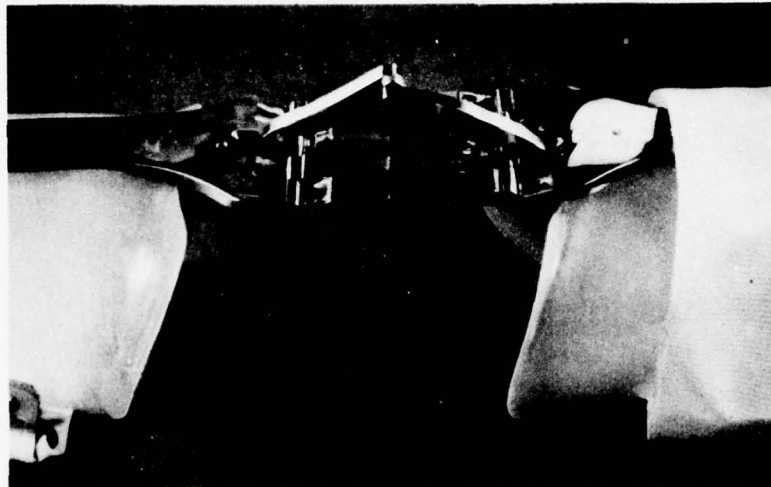


FIGURE 20. — The multiple-linkage posterior upright knee mechanism under development.

A representative example of orthotic cases treated by the team is reported as follows:

*Diagnosis:* Poliomyelitis with severe bilateral lower-limb paralysis.

*History:* This 30 year old female patient had poliomyelitis at the age of seven resulting in severe bilateral lower-limb paralysis. She had worn bilateral conventional KAFO's since that time. Her current orthoses were 17 years old but in good repair. They consisted of double uprights with drop ring knee locks, anterior knee pads, and limited-motion ankle joints. She desired lighter, more functional, and more cosmetic devices.

*Physical Examination:* Upper limbs normal. Lower limbs: poor-to-zero muscle strength below the hips bilaterally, good hip extensors bilaterally, fair hip abductors, and fair-to-good hip extensors bilaterally. She exhibited moderately severe genu recurvatum standing and walking without orthoses. She walked without orthoses, but had aching fatigue in the knees secondary to genu recurvatum and drop foot. In orthoses, she walked with a swing-through or labored four-point gait.

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FIGURE 21.—(a) Patient in his thermoplastic knee cage with flexible knee joint to damp knee motion, and (b) flexible cable knee mechanism for damping of knee motions, lateral view.



*Problem:* High energy expenditure and inefficient gait in 17-year-old orthoses, due to locked knees and weight of devices. It was decided to try to control knee hyperextension and foot drop with a lightweight and cosmetic device which would permit knee flexion during the swing phase of gait to decrease energy expenditure.

*Solution:* Bilateral KAFO's were fabricated from polypropylene, utilizing a posterior AFO design connected to an anterior supracondylar shell by means of reversed Klenzak ankle joints with pins and modified split stirrups (Fig. 22). The stops in the reversed ankle joints allow adjustability to permit just enough hyperextension for knee stability while still protecting against severe recurvatum. Free knee flexion is permitted.

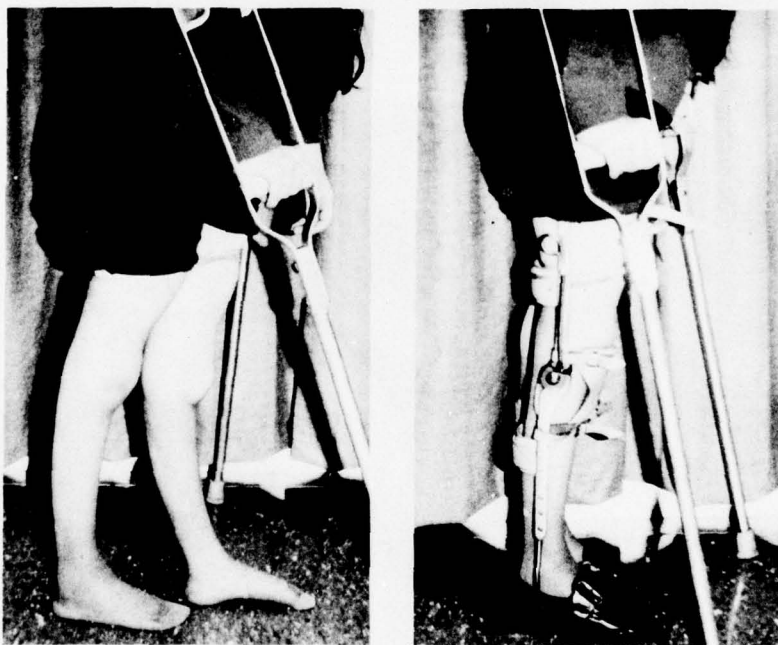


FIGURE 22. — (a) Above, left, the patient standing without orthoses. Note the degree of recurvatum that the patient exhibits without control of her knee joint. (b) The patient in her conventional metal upright orthosis. (See also Fig. 22 (c), (d), (e), and (f).)



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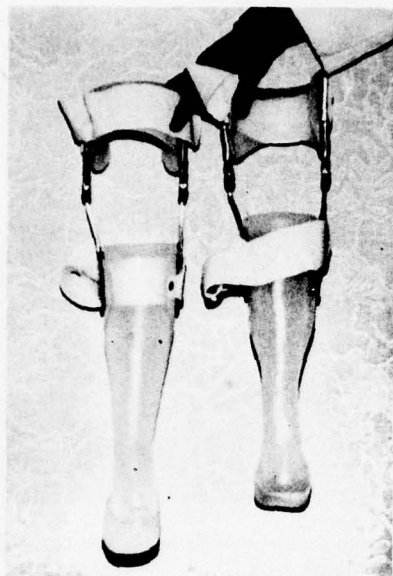


FIGURE 22. — (Continued) At left (c) the thermoplastic orthoses, and below (d) the patient ambulating in her thermoplastic orthoses. (See also Fig. 22 (e) and (f).)





FIGURE 22. — (Continued) Frontal view of the patient standing in her thermoplastic orthoses (e), and (f) the posterior view of the orthoses.

*Evaluation:* The patient ambulated at a rate of .39 m/s (meters per sec.) in her old orthosis. Her stride length was .60 m/c, (meters per cycle) and stride rate was .66 Hz. With the old orthosis, the barograph indicated that only a slight amount of weight was borne on the ball of the foot, but because of the contour of the bottom of the shoe (caused by the steel shank) it was impossible to obtain a reading from the pressure switches on the ball of the feet. When the patient ambulated without an orthosis, her ambulation rate dropped to .36 m/s, due primarily to the drop in her stride rate to .59 Hz. Her stride length remained the same at .6 m/c. Again, because of the contour of the bottom of her shoe, the pressure switches indicated only load being borne on the heel of her shoe.

With her new orthosis, the patient increased her ambulation rate to .49 m/s, stride length increased to .71 m/c, and stride rate increased to .69 Hz. Apparently due to the nature of the high heel on the shoe which the patient wore with her new orthosis, along with the dorsiflexion built into the new orthosis, there were no readings from the pressure switches on the ball of her feet, thus her foot switch sequence again showed only heel activity during ambulation in her new orthosis.

*Device Evaluation:* The patient felt that her new orthoses were excellent for working activities, very good for her home activities, and excellent for social activities: in each case, much better than her previous orthoses had been.

The patient felt that the durability of her old orthoses was about the same as that of her new orthoses.

She felt that she spent about the same amount of time on her feet with either device; however, it took less energy for her to spend a long time on her feet with the new orthoses because of their light weight. The patient felt that the new orthoses were highly superior in the ease of donning and doffing compared to her old orthoses. She also felt that her new orthoses were highly superior in comfort to the old orthoses and very much better cosmetically.

The team felt that the patient's new orthoses were very good in durability (no failures had occurred after 12 months of use) and the initial cost to the patient was considered satisfactory, probably similar to that of the old orthosis. In terms of function it was considered very good, and better than the old orthosis. Cosmesis was felt to be very good, and highly superior to the old orthosis. The new orthosis was judged to be easier to fabricate and fit than the old orthosis.

*Discussion and Summary:* This patient benefited greatly from her new orthotic design. She had, for some 23 years, been confined to relatively heavy metal double-upright lock-knee-type orthoses. Although these had been adequate to most of her needs, they did not present the ideal solution to her problem. The new devices are much lighter, much more cosmetic, and much more functional as demonstrated by her gait analysis (rate of ambulation increased by about 20 percent as did stride length and stride rate). From the cosmetic and comfort standpoints, her personal evaluation was that the new orthoses were highly satisfactory.

Our success with this type of orthosis once again illustrates the principle that the best orthosis is one which controls only the gait deviations, while allowing all normal functions to occur. In this case we were able to permit normal knee flexion and swing phase, and provide just sufficient hyperextension during stance phase for knee stability. At the same time we could protect the knee against the excessive genu recurvatum which would eventually have led to increasing deformity.

Control of the patient's bilateral drop foot was achieved by means of a posterior AFO shell. The reverse Klenzak ankle joint,



used as a knee hinge, provides a means of adjusting the degree of allowable knee extension. This adjustment is critical in a patient such as this.

Based on our experience with this patient, as well as others in the case studies, our opinion is that this type of orthosis may very well be the current orthosis of choice for this particular problem; i.e., the lower limb which is flaccid or flail with the exception of good hip extension, and which depends on hyperextension of the knee for knee stability.

Another device which has been reported to accomplish this objective is the Lehnis I.R.M. (Institute of Rehabilitation Medicine) SKA (Supracondylar Knee-Ankle) orthosis, made of plastic laminate. That orthosis, however, is heavier, does not distribute pressure on the anterior aspect of the thigh over as wide an area, and it protrudes well above the knee to the thigh level when sitting, since there is no knee hinge. Furthermore, it is not adjustable.

There still remains a question regarding the ultimate durability of the devices described as used for this patient. The present orthoses are now 12 months old, and there have been no breakage or repair problems.

#### Prosthetic Approach

The approach to prosthetic cases in general can be divided into two categories: the approach to residual limb problems, and the approach to ambulation problems.

For residual limb problems, the requirement was generally to redistribute weightbearing pressures away from areas of involvement, and as evenly as possible over viable areas of the residual limb. Techniques included modified air cushions, socket designs, windowed sockets, and modified suspension systems.

Ambulation problems included the high energy consumption of ambulation in bilateral AK amputations. The approach to these problems was to build lightweight short prostheses with rotators placed as far proximal as possible. Success is mixed, and seems to be related to patient age, motivation, length of residual limbs, etc.

A representative example of prosthetic cases treated by the team is reported as follows:

*Diagnosis:* Above-Knee Amputee, Absent Ischial Tuberosity.

*History:* This 38 year old white female sustained multiple injuries to both lower limbs with a resultant right above-knee amputation 1 year ago. Physical examination reveals exten-

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sive skin grafting over the proximal portion of the posterior thigh and buttock with absent ischial tuberosity. Previous prosthetic fittings resulted in ulceration and breakdown along the gluteal fold.

*Solution:* A modified quadrilateral suction socket with minimal posterior seat, narrowing of the medial lateral diameter and slight increase in the anterior posterior diameter was attempted (Fig. 23). Relief was created in the area of skin breakdown. A torque rotator unit was inserted in the shank portion.

The ulceration has almost completely healed. The patient wears the prosthesis all day and reports much greater sitting comfort.

*Evaluation:* The patient is ambulating well, now that her ischial ulcerations are healed. Gait is consistent in pattern and rate for short runs. Average rate of ambulation is .4 m/s with stride length .63 m/c and a stride rate of .64 Hz (average). The patient walks with normal foot-switch sequence on the normal limb, but spends very little time on the heel and medial side of the ball of her foot. On the prosthetic side, she never reaches the outside of her foot. She spends about the normal amount of time on the heel, but then spends all of the midstance in the beginning of double support time on the medial side of the ball of the foot and her heel. About half way through double support, she goes into heel rise on the prosthetic side and pushes off on the medial side of the ball of her foot, only slightly using her toe. The barograph showed a similar pattern of weight distribution with good step-through gait.

*Device Evaluation:* In the initial evaluation of the new prosthesis, patient felt that her work, home, and social activities were improved, along with comfort. Durability of the new prosthesis and the ease of donning and doffing were judged to be the same as the old prosthesis. Cosmesis of the old prosthesis was better than that of the new, but she was able to spend much more time on her feet with the new prosthesis.

After three months of wearing the new prosthesis, she evaluated all of the above in the same manner.

The team rated the durability of the new prosthesis the same as the old, after three months. The initial fabrication cost of each device was also the same. The function of the new prosthesis was rated better than the old, both initially



FIGURE 23. — (a) Above, patient showing ulcerated areas in the gluteal fold where the patient lacks an ischium for weightbearing purposes, and (b) the prosthesis the patient is wearing now, with a suction socket modified quadrilateral brim and rotator unit.





and three months later. Cosmesis of the new prosthesis was slightly worse and the initial cost to the patient slightly more than the old prosthesis.

The long-term cost of maintaining the two prostheses is believed to be the same, but because of the patient's increase in activity in the new prosthesis, there is an increase in the effort needed to maintain a good fit. This is due to continued stump shrinkage, attributed to the increased activity.

*Discussion and Summary:* The fitting of an AK amputation with absence of the ischial tuberosity requires weightbearing on the soft tissues of the residual limb. The residual limb presented posed the additional problems of scars and skin grafts in the area of the gluteal fold which were not conducive to withstanding the pressures of weightbearing. To overcome the problem of weightbearing on the fragile skin, and to prevent the problem of an adductor roll, the posterior proximal aspect of the quadrilateral socket had a generous radius and a narrow seat area to facilitate sitting. This is important because the patient is a typist and spends a major part of the day sitting.

The posterior wall was also relieved in the area of the ulceration. The torque rotator reduced the rotary motion between the residual limb and the socket during ambulation. The patient expressed a positive attitude toward the prosthesis in terms of comfort and function. Cosmetically, however, the rotator unit was not at first acceptable.

At 2 years, the patient is wearing the prosthesis routinely, and now presents a positive attitude toward the function of the torque rotator. The area of previous breakdown is well healed and poses no problem at this time. Liners have been added to the lateral wall of the socket to accommodate residual limb shrinkage, but the patient is losing weight and the residual limb is still shrinking. A new prosthesis is to be fabricated: at that time the rotator will be mounted just distal to the socket to improve cosmesis and weight distribution.

#### Results

Of the 33 patients included in the study, 11 have completed satisfactory fitting and initial treatment and have had at least 1-year followup evaluations. Of the remaining 22 patients, 4 have been lost to followup, 3 moved out of the state and have only remote contact, 4 have been recently fitted and are being followed

for the first year, 11 have been completed to the point where no followup is required. Fourteen patients currently require continuous followup. Four of these are listed as "complete" and 10 are not yet complete.

**Summary**

A total of 33 patients with difficult and unusual lower-limb problems are reported as to their orthotic and/or prosthetic management and the results obtained, with a minimum followup period of 1 year. Twenty-three orthotic and 13 prosthetic cases were included in this study.

This project demonstrates the effectiveness of a concerted team approach to the "problem patient" with limb disability, through individual solutions for each patient, and evaluation of the effectiveness of the prosthetic or orthotic solution. The team (physician, engineer, prosthetist, orthotist, and therapist) works closely together in all phases of problem identification, problem solving and solution evaluation, through the accumulation and analysis of both subjective and objective data.

When sufficient numbers of like clinical problems have been accumulated and the solutions to these problems have been analyzed, it is believed that it should be possible to make firm recommendations as to the optimum methods of management for these categories of limb disability.

In most cases of the kind selected for this investigation, optimum solutions cannot be obtained by conventional devices, but must be the result of design innovation. In the final analysis, proof of effectiveness of such non-standard devices must rest with the correlation of subjective and objective data gathered by a multidisciplinary evaluation team.

**Control of an Artificial Upper-Limb Prosthesis  
in Several Degrees of Freedom**

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During the first half of 1977, work on this project has centered on enhancing the reliability and the speed of a myoelectric recognition system for multifunctional-actuating above-elbow prostheses, via microprocessor hardware. This system uses a single electrode

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site for actuating several limb functions, on the basis of differences between identified time series parameters of the myoelectric signal for different limb functions.

During this period, U.S. patent No. 4,030,141 was awarded to the VA in the name of the present author as inventor ("Multi-Functional Control System for an Artificial Upper Extremity Prosthesis for Above-Elbow Amputees," award date: June 21, 1977).

Work on reliability enhancement included changing the microprocessor identification to a four-parameter autoregressive (AR) model form instead of the previous three-AR-parameter form, with the result that identification bias is reduced and thus discrimination accuracy is increased. Also, a longer word-length and faster hardware multiplier were incorporated into the Intel 8080 microprocessor system.

Lectures on the present system were given at Notre Dame University, Notre Dame, Indiana; Purdue University, West Lafayette, Indiana; and University of Michigan, Ann Arbor, Michigan. Also, several lectures and a colloquium were given at the University of California, at Berkeley. An invited paper describing the system was read at the Joint Automatic Control Conference (JACC) of the IEEE, ASME, SIAM, etc., in their San Francisco annual conference. All the above were accompanied by a movie presentation illustrating the performance of the discrimination system when used on-line with our Intel 8080 system. The test subject was an above-elbow amputee having 90 percent nerve and muscle damage of the residual limb.

Complete Fortran programs for the system, allowing it to be tested (off-line or on-line) on large-scale computers, are presently available at the Research Center for Prosthetics of the VA in New York. The programs are also available from the author. These Fortran programs can be tested using raw EMG recordings either on-line or off-line, via digitized tape, on any large-scale computer.

**Acceleration of Bone Healing by Electrical Stimulation**  
Helen Hayes Hospital Biomechanics Research Unit  
Route 9-W, West Haverstraw, New York 10933  
George Van B. Cochran, M.D.

The Surgical Research Service at Castle Point VA Hospital and the Biomechanics Research Unit at Helen Hayes Hospital have undertaken a cooperative project designed to test various parameters of electrical stimulation on a model of non-union created in



canine ulna. Work is now proceeding on a series of dogs, utilizing new stimulator and electrode systems developed at Helen Hayes Hospital. Work on the first four animals has now been completed and specimens are undergoing decalcification prior to evaluation. Additional experiments in the series now are scheduled on a regular basis.

Specifically, the project is designed to determine the effects of electrode location within a bone defect, and the effects of current density on healing of this standard model for non-union.

**Hemodynamic Evaluation of Postoperative and  
Preoperative Amputees**

**VA Hospital**

**Castle Point, New York 12511**

**Bok Y. Lee, M.D., Frieda S. Trainor, Ph. D., and**

**David Kavner, D. Eng.**

Work has been completed for this program's first report of quantitative data for arterial blood flow in the lower limbs. Measurement of peak pulsatile blood flow for the thigh and calf has been done with the noninvasive electromagnetic blood flowmeter. Data are presented showing correlation of results using electromagnetic flowmetry, segmental Doppler systolic pressures, and arteriography. In this report 100 limbs have been categorized based on the patient's complaints: (i) asymptomatic, (ii) intermittent claudication, and (iii) rest pain, gangrene, and ulceration. Mean values and coefficients of variation for arm and ankle systolic pressures, the ischemic index, and thigh and calf peak pulsatile blood flow have been calculated. Significance has been tested between all three groupings using the t-test.

Table 1 summarizes some of the pertinent data obtained for the report.

A high degree of significant differences for thigh and calf blood flows was obtained for the three groups. From these data for calf blood flow, patients are divided into three discrete clinical categories corresponding to the chief complaints. In numerous instances, the noninvasive electromagnetic flowmeter provides information which cannot be obtained using segmental Doppler systolic pressure measurements. For example, in patients with grossly exaggerated ankle pressures due to severe hardening of arteries, the peak pulsatile flow provides the most accurate information: Doppler systolic pressures in these instances cannot be interpreted; however, the noninvasive flowmeter is not influenced by the hardened vessels

TABLE 1

	Group I	Group II	Group III
	Asymptomatic	Intermittent claudication	Rest pain Gangrene Ulceration
	(26 limbs)	(38 limbs)	(36 limbs)
Arm	124 mm Hg	136 mm Hg	136 mm Hg
Ankle	145 mm Hg	92 mm Hg	58 mm Hg
Ischemic Index	1.2	0.68	0.45
EMF Peak Pulsatile Flow in:			
Thigh	383 ml/min	166 ml/min	112 ml/min
Calf	130 ml/min	44 ml/min	44 ml/min

and flow in the vessels can be obtained. (As can be expected in these instances, the flow is somewhat diminished.)

The noninvasive electromagnetic flowmeter is particularly useful for patients with multiple occlusion (i.e., femoro-popliteal plus aorto-iliac) and the site of obstruction can be predicted. If peak pulsatile flow for the thigh region shows acceptable arterial inflow from the aorto-iliac area, then the femoro-popliteal bypass procedure is indicated. If the peak pulsatile flow is reduced at the thigh and the patient's symptoms include a combination of complaints (claudication, rest pain, gangrene or ulceration secondary to aorto-iliac occlusive disease)—then an aorto-femoral bypass is indicated. Once arterial inflow is brought to the level of the profunda-femoris artery, there is considerable improvement in the patient's complaints.

The implications from these data are that noninvasive quantitative measurements of blood flow in the limbs can provide the information for accurate decision-making leading to better care of the patient with vascular disease, and a consequent salvage of many limbs.

**Maxillofacial Restorative Biomaterials and Techniques**  
**Temple University School of Dentistry**  
**Broad and Montgomery Ave., Philadelphia, Pa. 19122**  
**John F. Lontz, Ph. D., and James W. Schweiger, D.D.S., M.S.**

The activities of this research on maxillofacial (more properly termed orofacial) biomaterials, and on techniques for producing "safe and effective" prostheses, are summarized by topic in a Comprehensive Development Plan presented here as Table 2.

TABLE 2. — *Comprehensive Development Plan<sup>a</sup>*

I. Product Development
Principal materials (polymers, elastomers) selection
Defined ingredient composition and critical processing (polymerization, curing)
Selective testing and replication of living system
Durability (end-use) testing: environment, exposure and maintenance
II. Fabrication Techniques
Determining critical temperature-time factors
Designing forming (molding) components or equipment
Standardization of applied processing (curing) variables
Modifications in fabrication for complex structures
III. Pigmentation and Cosmetic Matching
Development of appropriate, simple measurements
Developing dispersion into prosthetic materials
Spectral assignment (registering) of selected pigments
Color-stability testing against light exposure and maintenance
IV. Toxicity Testing
Develop direct approach to orofacial tissues (maxillofacial)
Accumulate a cohort of excised oral (gingival) tissues for preliminary tests in tissue culture techniques — explore variables
Develop biochemical and biophysical complements to culture techniques
Extend to correlations with critical processing conditions (Phase I and II)
V. Field (End-Use) Evaluation of Fabricated Prostheses (Clinical, Rehabilitative)
Select representative and competitive participants
Develop criteria for preference or acceptance (wearer)
Assess merits and deficiencies for referral to Phases I, II, and III.

<sup>a</sup> This is merely a topical listing of programs, by phase and with descriptions of R&D efforts: as they are initiated, programs are assigned a time-table for the monitoring of such features as starting, reviewing, etc., and time-costs.



There is priority for the toxicity-testing and field (end-use) evaluation necessitated by the impact of the recent Toxic Substances Control Act (TSCA) (1). Simultaneously with the continued development of a quality-dependable silicone elastomer formulation cured under strictly defined polymerization conditions, there is the effort on biological proof of safety in terms of observed growth of specific human cultured tissues.

At the same time, the broadened field evaluation for clinical appraisal of the intrinsically pigmented silicone elastomer has been in progress, to resolve competing claims of superiority for diverse polymer types.

Underlying all of these activities is the unequivocal chemical and physical description (and description of procedures of fabrication) for all ingredient materials, as frequently reported in numerous presentations (2, 3, 4, 5).

The coverage of the present research is unusual in that it extends from materials sciences and prosthetics technology to clinical affirmation of "safe and effective." (It should be noted that the basic polymer selected for this program is one that has been approved by FDA for commercial applications such as gaskets, etc., in food-handling and processing equipment where it is in sustained and intimate contact with food.)

#### **Developments**

Specification testing extends from the simple biomechanical tensile constants, and specified colorants, to measures for assuring biological compatibility through tests on cultured gingival tissue, with the ultimate goal being clinical proof of prosthetic effectiveness.

##### ***1. Tissue Culture Test Development***

A test procedure has been developed using excised human gingival tissue grown under conditions optimized for discriminating between biomaterials for which there are previous reports (6) of levels of toxicity. The development involves adapting well-specified, documented procedures for (i) visual observation of fibroblast growth (Fig. 24), (ii) specifying growth and maintenance media, (iii) morphological characterization of the fibroblast through scanning electron microscopy (SEM), and ultimately (iv) genetic cell changes.

These developments bring to the problem of demonstrating that a material is "safe and effective for humans" criteria based directly on actual human tissue, including samples selected from the specific

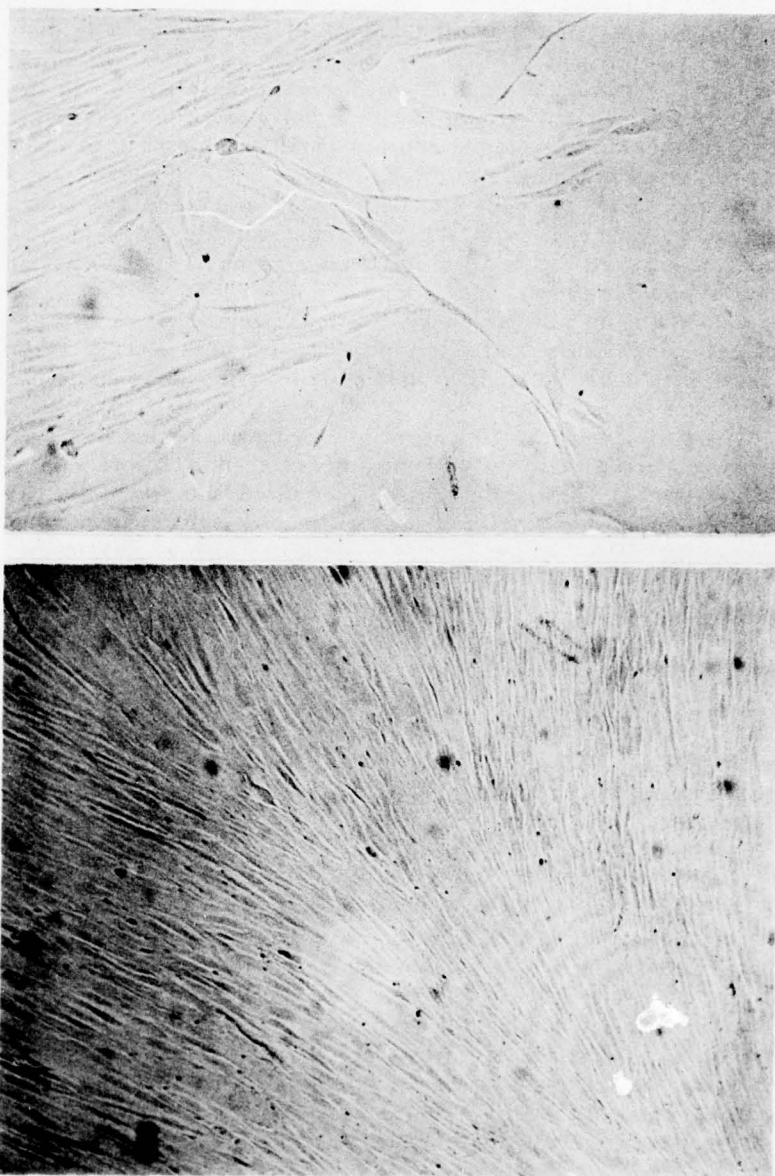


FIGURE 24. — Typical human gingival fibroblast cells: (a) peripheral growth initially (first passage), and (b) continued mature growth. Magnification is 105x. The subject is a 60-year-old white male with Parkinson's disease.

patient to be fitted with the prosthesis. They thereby eliminate the problem of the relevancy of pre-clinical animal testing.

## **2. Field Evaluation**

An indispensable phase of the development of an effective prosthesis is the evaluation from patient/wearer experience, conducted at several locations to offset subjective attitudes that may be prevalent in specific clinics and centers. Therefore, an extra-mural evaluation program has been initiated whereby this project provides a range of HTV polysiloxane fabricated prostheses for nose, ear, orbital, and internal oral reconstructions down to the esophagus, for actual patient wearing. The range of prostheses is supplied in a range of yellow-to-red color indices. Thus far, one Veterans Administration Maxillofacial Clinic (New York) and two non-VA maxillofacial clinics have been provided with more than 30 diverse intrinsically-pigmented prostheses, involving at present 9 cases.

This effort has been made possible by the previously reported accomplishment (5) in adapting the HTV polysiloxane to curing in ordinary dental stone molds, thereby eliminating the expense, time, and special skill that were required when metal molds had to be used.

This extra-mural portion of the Comprehensive Development Plan can support up to eight outside maxillofacial clinics, for 1 or 2 years, based on the capability of making up to 16 prostheses per day. That is enough to take care of all estimated orofacial cancer cases for the Veterans Administration. Significant savings are possible, compared with current cost levels for work done in small-shop, often one-man, facilities.

## **Accomplishments**

Reviewed in the order of Table 1, the accomplishments involve the following:

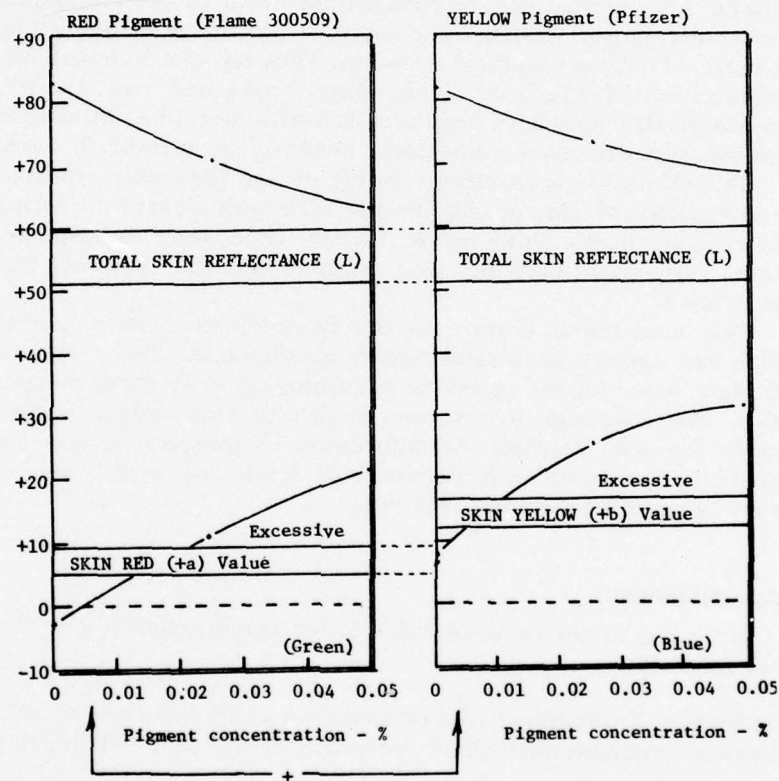
1. *Product development* of a material composition from a reliable, low-cost, available, high-quality polysiloxane elastomer (GE 4524U);
2. *Development of a simple fabrication technique* that can be carried out in a dental laboratory. (These efforts will require still further investigation.)
3. *Pigmentation and Cosmetic Matching.*

Instead of depending on proprietary pigment sources, which would mean composition and concentration would be undisclosed,



the effort has been to use pure, commercially specified and defined pigments, to which the measurement of reflectance and the proportion of red vs. yellow can be applied and reproduced universally. In addition to U.S. sources of pigments, a series used in European prosthesis cosmetic-matching has been included in this program.

Figure 25 illustrates the concentration-dependent color reflectance from which, by arithmetic proportioning, the matching with human skin can be predicted and thus competently matched by the prosthetist.



(C) Arithmetic proportion for INTRINSIC coloration.

FIGURE 25. — Concentration-dependence plots of two standard commercial pigments matching the two essential skin pigments, namely hemoglobin red (with FLAME 300509) and carotenoid yellow (OXIDE YELLOW — Pfizer). The arrows at "C" indicate in a general way the arithmetic proportions of the pigments to attain intrinsic coloration of a prosthesis, to be finished by final extrinsic cosmetic matching. Heat-cured (HTV) polysiloxane elastomer-oligomer formulation was used as base.

#### 4. Tissue Culture Testing

During this period 28 human gingiva tissue samples have been collected and used to develop a fibroblast growth procedure, adapted from the numerous techniques (mostly for animal tissue) described in the literature. A significant accomplishment in this program has been the adjustment of sustaining nutrient media by which it is possible to grow human gingiva fibroblast cells reproducibly, with the cells having been taken from a single human (patient) source. These cells and a cohort of other patient cells are now being accumulated to establish the method's applicability to a broad range of patients of all ages, races, states of health, and degrees of exposure to cancer-controlling radiation. The 28 gingival tissue samples already collected represent a patient age range from 19 to 72 years, white and black racial groups, and various states of health.

In studies using (i) known non-toxic Teflon, and (ii) known toxic PVC, and comparing their effect on mouse fibroblast with their effect on human gingival fibroblast, preliminary results have revealed a significant difference in the rated toxicity to the extent that the mouse fibroblast tests do not conform to the results with human gingival fibroblast. This implies that the mouse fibroblast may not be required and, in fact, should be eliminated owing to its non-conformance with the results observed with human gingival tissues. For this reason, as stated earlier, a collection or cohort of various species-individual tests must be performed. This effort, still in progress, is to be reported on in succeeding reports.

#### 5. Field Evaluation

As mentioned earlier, intrinsically pigmented, fabricated orofacial prostheses are being sent to VA and non-VA maxillofacial reconstruction participants. The procedure involves this laboratory first receiving either a wax model, a formed prosthesis, or even a photograph. Prostheses, reconstructing noses, ears, orbits, and internal sections, involving 12 patient reconstructions, have been sent out since March 1977. The results in terms of wearer acceptance (or dislike for any reason) and inspection of returned prostheses for quality defects, constitute an important feature of this phase of the project. In due course this feedback will be the subject of a report.

#### References

1. Editorial, Science Vol. 192, p. 1216, *Medical Devices Act of 1976*, an amended and toughened regulatory law on medical devices that requires proof of safety with data to be reviewed for each individual case by special panels. This now imposes stricter

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requirements on proving "safe" in terms of toxicity or some form of harm, and "effectiveness" which implies useful service and durability, including any handling, such as cleaning with scouring agents and deodorizing agents that require chemical stability of the biomaterial to assure in turn "safe" quality.

2. Lontz, John F., James W. Schweiger, and A. William Burger: Development and Standardization of Polysiloxane Maxillofacial Prostheses. Presentation at the Twenty-Second Annual Meeting, American Academy of Maxillofacial Prosthetics, November 1975, Williamsburg, Virginia.
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6. Rosenbluth, S. A., and Co-workers. Tissue Culture Method for Screening Toxicity of Plastics Materials to be Used in Medical Practice. *J. Pharm. Sciences*, 54: 156-159, see also 54: 1545-1547, 1965.

**Permanently Attached Artificial Limbs**  
**Southwest Research Institute**  
**8500 Culebra Road**  
**San Antonio, Texas 78284**  
**C. William Hall, M.D. and William Mallow**

### **An Involuted Intramedullary Skeletal Extension**

#### *Introduction*

A previous report in the Bulletin (BPR 10-27, Spring 1977) described the "involuted" approach for bringing a skeletal extension through the skin. This approach had been adopted to alleviate the problem of skin retraction about a direct skeletal extension penetrating the integument. Skin acts like an elastic membrane in that biaxial forces will cause a pre-existing hole to enlarge. The involuted approach places the three skin-penetrating lugs of the skeletal extension in position to exit at points of uniaxial skin stress.

#### *Methods and Results*

Several models of the involuted bucket-type prosthesis were designed, although the last design (Fig. 26) was the only one used in quantity. Twelve of these later designs were implanted, with bone cement used to anchor the prosthesis to the tibial stump.



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#### Other VA Research Programs

As was predicted, all had problems caused by necrosis of the distal 1-1½ cm of the tibial stump. This was of relatively little concern, since the experiment was designed to test the new skin-penetrating technique and not to address itself to the bone-interfacing problem.

None of these 12 implants showed any tendency of the skin to retract from the penetrating lugs. There was some tendency for the distal 1-2 cm of the skin to mummify, which demonstrates the necessity of having a short skin flap. These results were the same regardless of the skin-interfacing material, which consisted of either nylon velour, Orthoplate® carbon, or Proplast®.

Once the skin retraction problem appeared to have been solved, it was considered timely to move into other facets of this complicated program. Due to the demand for keeping a short skin flap, it was necessary to shorten the cup. The optimum way of shortening the cup was to return to the intramedullary approach. Because of the problems associated with disruption of the nutrient artery

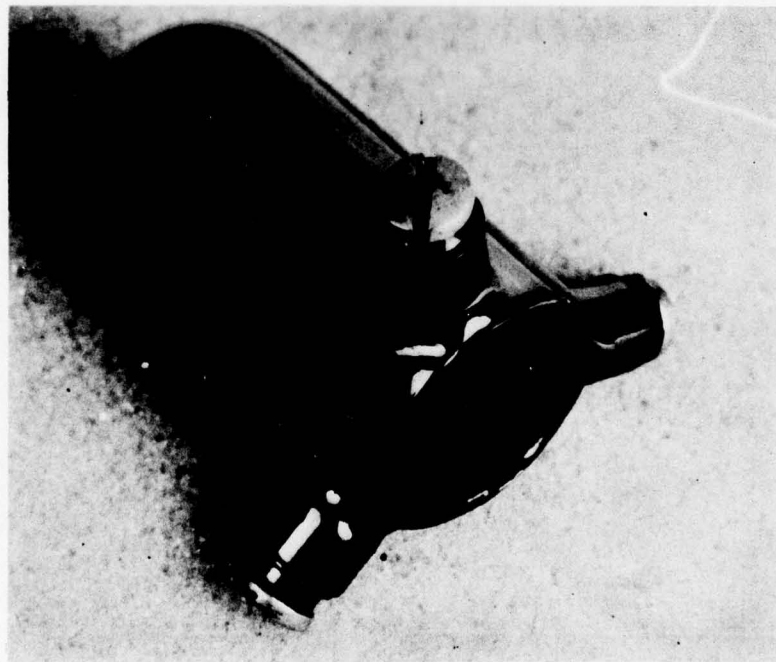


FIGURE 26. — This tri-lugged involuted bucket has been coated with Orthoplate® carbon by General Atomic Company. Buckets similar in construction were also coated with nylon velour, and others with Proplast.®

and its tributaries, we naturally experienced some ambivalence about returning to the intramedullary approach.

Rhineland, (3) however, has demonstrated that the intramedullary circulation can be either maintained or reestablished by the use of a Schneider nail coated with Proplast.<sup>®</sup> Therefore, it appears feasible to use a device similar to the Schneider nail, with a short cup attached to the distal end which would hold the three percutaneous lugs. Such a device has been fabricated, and two have been implanted into the tibia of goats. The first such implant had an uncoated Schneider nail, with the attached bucket and lugs coated with nylon velour. The second implant had the Schneider nail coated with Proplast<sup>®</sup> (Fig. 27).

The uncoated prototype was used mainly to test the design concept and to determine if any modifications in the surgical technique would be necessary. This animal was sacrificed after 6 weeks and was found to have a loosened prosthesis. Since the intramedullary Schneider nail had not been coated with an interfacing material, loosening of the rod was predictable. The skin showed no retraction about the lugs and no tendency to mummify.

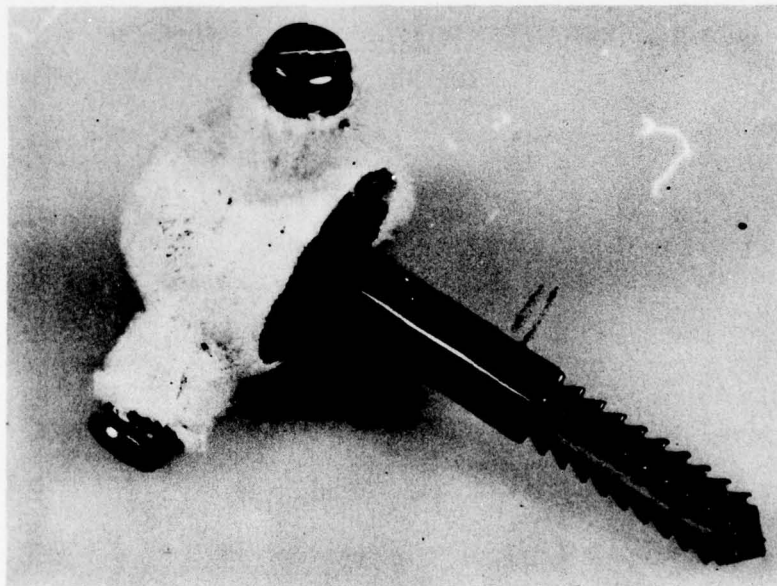


FIGURE 27. — This tri-lugged involuted intramedullary prosthesis has the Schneider nail coated with Proplast<sup>®</sup> in its channels, and has the bucket and lugs coated with nylon velour.



#### Other VA Research Programs

A slight modification is being made in future models, in that the intramedullary nail will be trifluted, rather than quadrafluted. This will give the nutrient vessels more space within the intramedullary canal.

#### Summary

The hypothesis set forth to explain the problem of skin retracting from a direct percutaneous skeletal extension appears to have validity. When the involuted tri-lugged approach has been used, no skin retraction has been observed. Because mummification of the skin can occur if the skin flap is exceptionally long, it became necessary to redesign the involuted prosthesis and to shorten the cup. That resulted in a return to the intramedullary approach, utilizing a modified Schneider nail. This, it is hoped, will allow reestablishment of the intramedullary circulation. The new design is being coated with a variety of materials, including Proplast,<sup>®</sup> Ortho-plate<sup>®</sup> carbon, bioglass, and velour. Within the next 6 months, it should be determined whether or not a successful marriage has been performed to accomplish both proper skin-interfacing and proper bone-interfacing simultaneously.

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3. Rhinelander, Frederic W.: Vascular and Histologic Effects of Implantation of Biomaterials in Bone. Keynote address, 2nd Annual Meeting of the Soc. for Biomaterials, Phil., Penna., April 13, 1976.

**Mobility Engineering for the Severely Handicapped**  
**Mobility Engineering and Development (MED), Inc.**  
6905 Shoup Avenue  
Canoga Park, California 91306  
Charles M. Scott and Ronald E. Prior, Ph. D.

#### Van Compatible Wheelchair

Road-testing of the first preproduction model chassis has been completed, to a point where sufficient test information is available to finalize the chassis design for the next three clinical test units. Many changes in the chassis were made to improve performance and ability to handle rough terrain. An estimated 400 miles were covered during the rough terrain testing, including an open field and a prepared obstacle course. The obstacle course included mul-

tiple obstructions, triangular in shape, 2½ in. high, alternating right and left, as well as wheel ramps with 3-in. drops.

The only structural problems occurred in the raise-and-lower actuator system: there, the design now includes an improved traveling-ball linear actuator with greatly strengthened attachment points.

No structural failures of the suspension occurred during the testing, nor were any problems detected at tear-down. Unsatisfactory wear occurred only at the bronze-bushed joints in the forward control arm bushings. This area has been redesigned to use tapered roller bearings, so that adjustment for wear can be accomplished.

The performance of the rubber torsion springs was of interest. Their performance on the rough terrain tests was excellent: the natural damping of the rubber made the ride surprisingly soft without the excessive bounce which had been expected. They also absorbed lateral shocks, which greatly reduced the stress on structural members without creating any control or stabilization problems.

All engineering drawings are now complete. The second-generation chassis is now 80 percent complete.

The electronic control package performed well during testing, but all services were not functioning during the tests. The areas still under development are: (i) reduced speed at high seat elevations, (ii) variable steering versus forward speed, and (iii) limited reverse speeds. All of the advanced circuitry is bench-tested and is now being installed on the test unit for road testing.

#### **Electronically Controlled Van**

The long procurement delay on the computer components is now over. The unit is assembled and debugging is under way.

The components for the hydraulic and electronic servomechanisms have been selected and ordered. The preliminary hydraulic layout is complete. Complete bench testing will precede installation in the vehicles.

MED expects to move into new facilities approximately September 1, 1977. This will bring the electronic lab and vehicle assembly room adjacent to each other, permitting direct electrical connection between the vehicle and the electronic development equipment. This will greatly improve the efficiency of the operation.

**In Vivo Loading of Knee Joint Replacement**

**Biomechanics Laboratory  
Bingham Engineering Building  
Case Western Reserve University  
2040 Adelbert Road  
Cleveland, Ohio 44106**

**Richard H. Brown, Ph. D., Kingsbury G. Heiple, M.D., and  
Victor M. Goldberg, M.D.**

The Veterans Administration orthopedic departments service two types of patients with arthritic knee difficulties. In the first category are those with disabling rheumatoid arthritis. The second category contains those with degenerative arthritis usually on the basis of prior trauma. This second group contains men still at working age who possess work capabilities. Their knees are exposed to heavy loading situations.

Currently designed prostheses have been developed for the older age group and for other patients with disabilities such as rheumatoid arthritis. The load data developed in this present study will aid in understanding the types of loads that may be permitted in the younger working patients. Engineering design data will be produced that should allow for better prostheses from the standpoint of load, life, and fatigueability.

This project will also aid in the rehabilitation of patients following knee arthroplasty and other disorders about the knee joint, by revealing the loads the knee joint is exposed to with such activities as ambulation, assisted ambulation, exercise, and the activities of daily living. The data will be further useful in ascertaining some of the underlying pathomechanics of knee disorders.

During this report period, major technical difficulties were encountered during manufacture of unicondylar knee prostheses to be used for telemeterized knee implantation. The difficulties involved welding of two of the mechanical subcomponents. The welded junction, which is located outside of the region of major stresses, required the development of some new technology in conjunction with N.A.S.A. Lewis Research Laboratories. Development of this new technology required approximately 6 months, and therefore required the modification of our work schedule. The technical development necessary to produce necessary acceptable weldments was accomplished.

Unfortunately, during the next stage of the development of the unicondylar prosthesis, significant additional problems were encountered. Specifically, the devices were sent out to a commercial polishing firm, recommended and routinely used by commercial



manufacturers, to polish the devices to the necessary degree of sphericity and surface finish for acceptable implants. The firm chosen encountered significant difficulties in accomplishing this task, and in fact, actually ruined two of the units beyond any hope of salvage. The remaining units are of suspect quality at this time. It is felt by the present investigators that for technical reasons these should be considered unacceptable for long-term implant in human subjects. (These units were, however, salvaged and installed in cadavers without loading them, to gain experience in surgical technique.)

Several reasons for the problems in polishing were given. Due to the custom-made nature of these designs and the lack of normal polishing and holding jigs that would be used in such sphericity grinding and polishing, unusual difficulties were encountered. We shall have to consider this carefully in trying to achieve an acceptable implant for human use as we redo this portion of the work. We are held to a standard for human implantation equal to or better than that of the present commercially acceptable, available units, and this imposes very stringent requirements and unusual difficulties on the manufacturing of a telemeterized implant, for use in a human subject, that can pass both our own Human Experimentation Committees and our own personal standards. Therefore, as a result of this unfortunate experience, the remanufacturing process for the proposed new series of 15 units will be conducted keeping in mind the end necessity of having these devices passivated and polished. We will, therefore, include the necessary manufacturing and jigging for these new devices, and those jigs and devices necessary to utilize commercial polishing procedures on the remanufactured implants, and will insure that all necessary mechanical holding and polishing criteria are met before attempting further work on the units. If necessary, one of the investigators in this project will personally supervise this operation either at Case, or at the commercial polishers on site.

#### **Other VA Research Programs**

##### **Research and Development Project on Advanced Orthotic Devices for Adult Paraplegics**

**Prast Research Associates, Inc.  
1094 Stony Point Road  
Grand Island, New York 14072  
Martin T. Prast**

**School of Engineering  
University of Colorado  
Boulder, Colorado 80302  
Lawrence E. Carlson, Ph. D.**

Prast Research has completed production of four new PACO III units for testing by paraplegics in the VA system.

The new units will be distributed to four locations in the country: one to Boulder, Colorado (to be followed up by Lawrence Carlson), one to Lubbock, Texas, one to Buffalo, New York (to be followed up by Mr. Prast) and the fourth to VAH, Castle Point, New York.

##### **Engineering Applications in Orthotic and Prosthetic Treatment of Musculoskeletal Defects**

**Motion Study Laboratory  
Rehabilitation Medicine Service  
Veterans Administration Hospital  
10701 East Boulevard  
Wade Park, Cleveland, Ohio 44106  
E. Byron Marsolais, M.D., Ph. D., and Edward Schulz, E.E.**

##### **Three-Dimensional Automated Motion and Joint Force Analysis**

###### ***1. Three-Dimensional Stroboscopic Gait Analysis System***

This system was developed to serve as a prototype for studying the techniques, used by such other investigators as Paul (1), Morrison (2), and Bresler and Frankel (3), for the estimation of forces in the hip and knee joints.

*Progress.* Since the configuration of the system components for this technique is identical to that of proposed totally automated system, its value as a prototype has been significant. The computer analysis has been thoroughly worked out and several of the errors that existed at the beginning of this reporting period have been eliminated.

Several analyses have been performed on normal subjects and computer presentations of results in both graphic and tabulated form have been worked out. Some of the kinds of computer-generated graphics possible are shown in Figure 28.

The stroboscopic gait analysis system was moved to the Veterans Administration Hospital from the Biomechanics Laboratory, Case Western Reserve University, at the start of this reporting period. Since then, it has been reassembled. A new wider and lower walkway has been constructed, and three normal knee joint studies have been performed. The results obtained, in general, corroborate Morrison's results but some discrepancies do exist. One of the most questionable aspects of this analysis, in both Morrison's and our system, concerns the electromyographic data. The difficulty is in determining the start and end of muscle activity for a specific muscle group during a gait cycle. Variability from one cycle to the next is significant. This problem has been studied and several improvements have been made, as follows:

1. Electrode placement has been studied and optimum spacing and positioning determined;

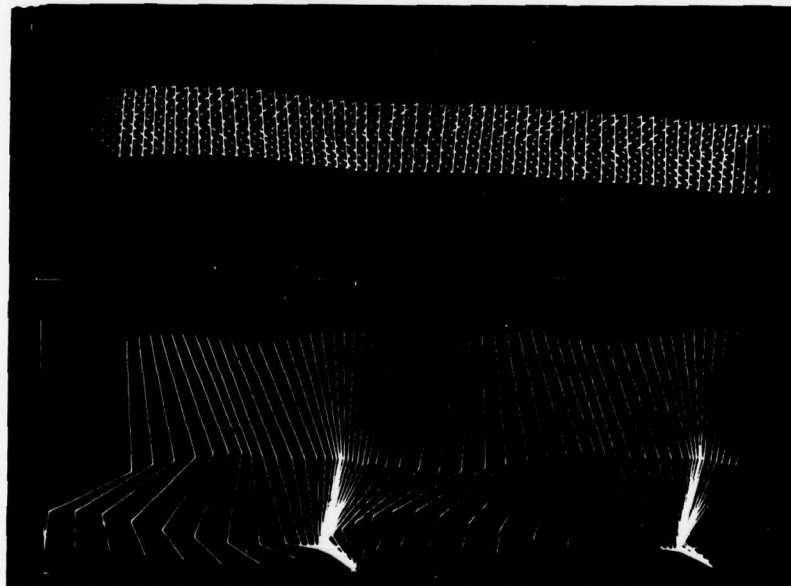


FIGURE 28a. — Top: Progression of triangles representing the three pelvic markers, during normal level walking, as seen from above. Bottom: Progression of stick figure representing the right pelvis, knee, ankle, and toe markers, during normal level walking, as seen normal to the walkway.



#### Other VA Research Programs

2. Significant filtering is applied to eliminate unwanted signals;
3. The raw EMG is rectified and integrated to provide a more interpretable signal; and
4. Use of intramuscular electrodes has been studied and far superior results are indicated.

The entire knee analysis computer program has been rewritten to run on our PDP 11/45 computer system, and the programs to generate computer graphics of results have been written and tested. The graphics programs have been found to be valuable in locating errors generated during data reduction and analysis procedures. They have also proved invaluable in understanding the significance of results. A graphic data digitizer has been interfaced to the computer to allow direct entry of X-Y coordinates of kinematic data from multiple exposure pictures produced during the stroboscopic analysis. This results in a four-fold reduction in time required to complete this process.

*Conclusions.* Although this is a fully functional system, its value as a clinical tool is limited because of the tremendous effort necessary to arrive at the final results. This effort is necessary primarily

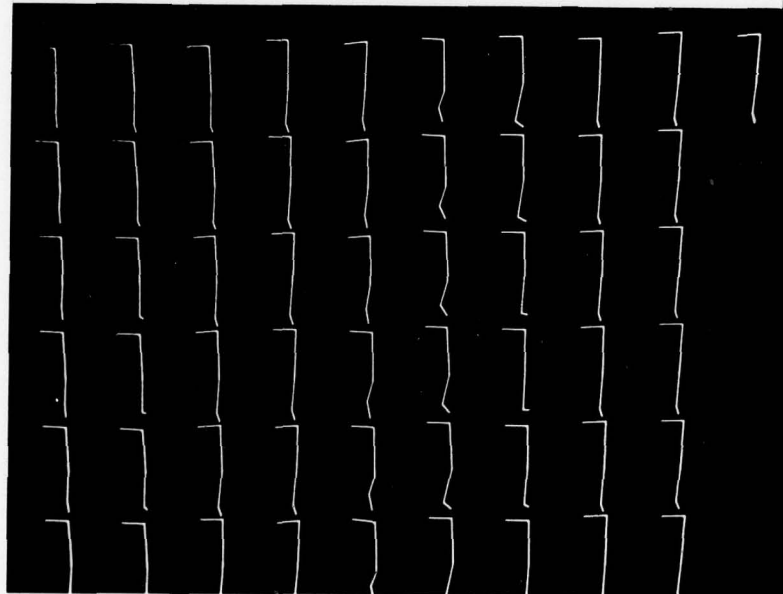


FIGURE 28b. — Frame-by-frame stick figure representing the rear pelvis, right pelvis, knee, ankle, and toe markers during normal level walking as seen from the left end of the walkway.

because, with this system, kinematic data reduction cannot be automated. Each evaluation involves thousands of measurements and therefore results are sometimes not available until several weeks after the gait analysis was performed in the laboratory. However, as a prototype, this system has served its purpose excellently.

Use of the strobe system will be limited to occasional studies for systems comparisons and possibly to study the effects of having a subject encumbered by cables or gear carried by him.

## 2. Automated Three-Dimensional Motion and Joint Force Analysis Using the Selspot<sup>a</sup> System

A gait analysis, such as is involved in estimating forces in joints and related muscle groups and ligaments, necessarily results in a great volume of data. Unless the collection, reduction, and analysis of this data can be automated, the clinical application of such a measurement technique is not realizable. Incorporation of elec-

<sup>a</sup> Motion monitoring system manufactured by Selcom, A.P.B., Sweden.

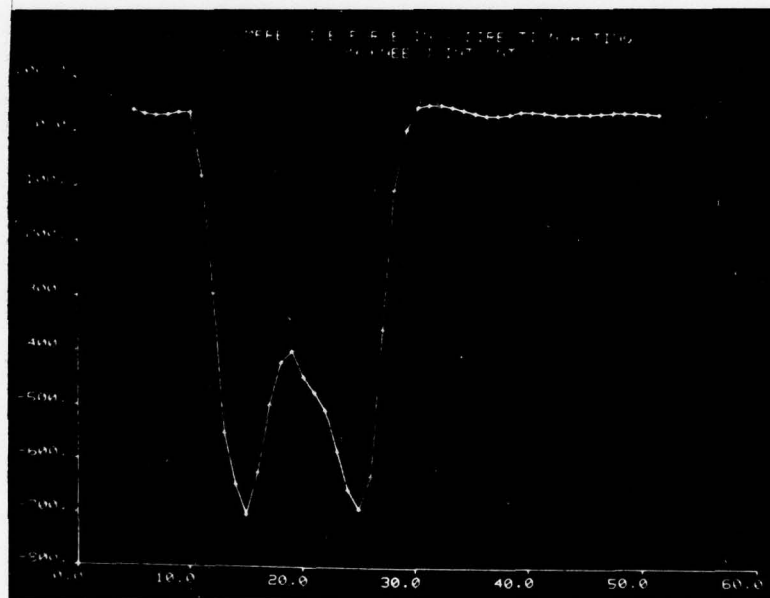


FIGURE 28c. — Compressive force in the knee joint during normal level walking as a function of the strobe flash number. (Heel-strike occurs at flash 10 and toe-off at flash 30.)

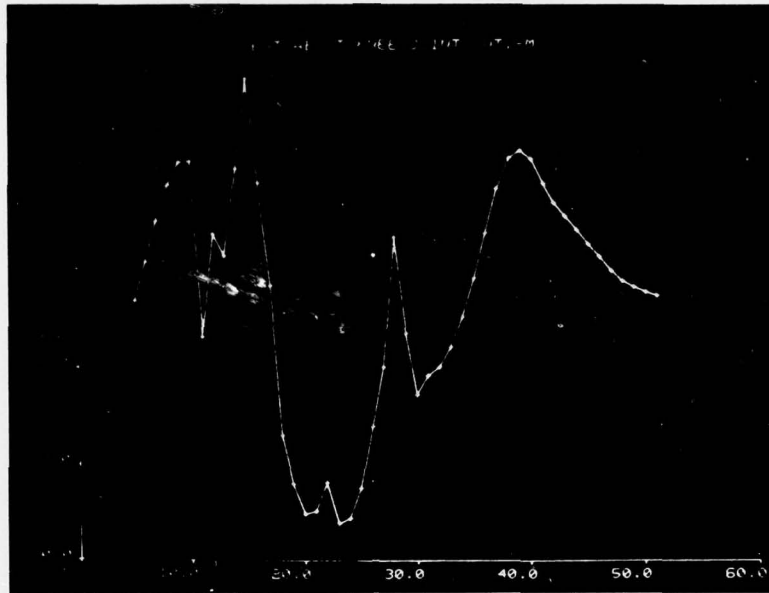


FIGURE 28d. — The moment normal to the plane of progression acting at the knee joint during normal level walking as a function of the strobe flash number.

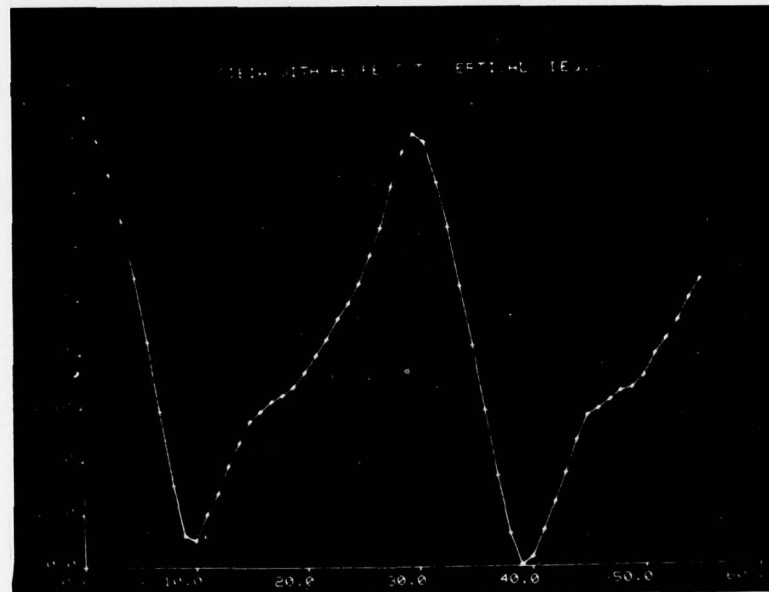


FIGURE 28e. — Position of the tibia in the plane of progression, with respect to the vertical, as a function of the strobe flash number.



tronic cameras, such as are used in the Selspot System, and an on-line computer system, allows such total automation.

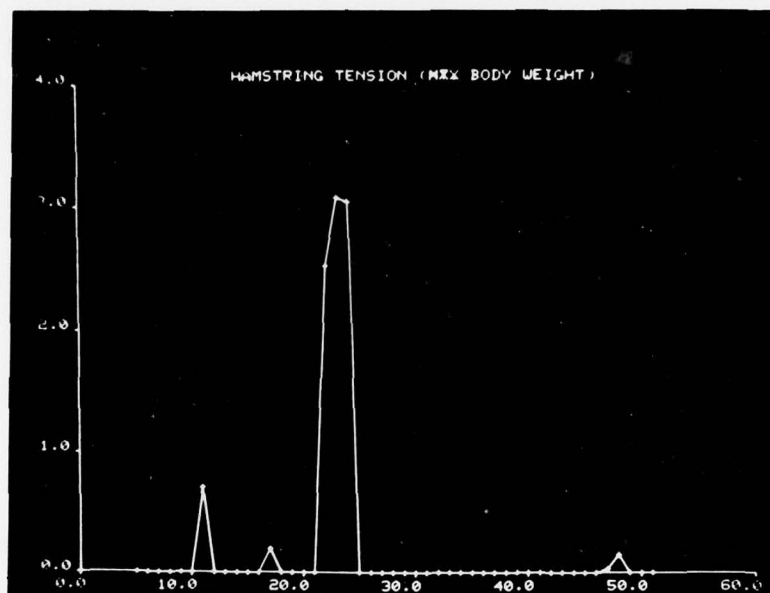


FIGURE 28f. — Hamstring tension during normal level walking as a function of the strobe flash number.

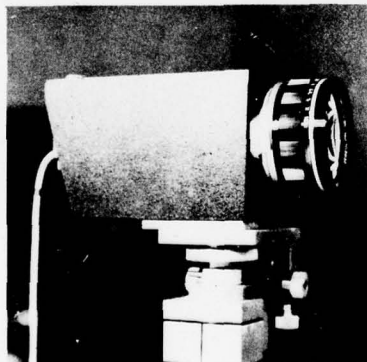


FIGURE 29. — Selspot camera mounted on the adjustable camera head.

#### Other VA Research Programs

*Progress.* Camera pedestals have been installed and camera heads fabricated which allow accurate alignment of cameras (Fig. 29). The Selspot cameras have been tested in their intended orientation (Fig. 30) to determine the capabilities of the system.

Three-dimensional gait analysis, it appears, is one of the more complex applications of this system and taxes it to its limits. In fact, the system as purchased is not adequate for a gait analysis of this kind. The results of our studies, thus far, have yielded the following information:

1. The primary weakness of the system is due to insufficient intensity of the infrared-light-emitting diodes provided. These are the light sources which are mounted at the various anatomical targets to be monitored during a gait analysis. Even if the LED's provided with the system are aimed directly at a camera, they cannot be accurately monitored at the most distant points of the analysis.
2. The power requirements to drive the light-emitting diodes are significant. Without design changes, battery powered operation of LED's is not reasonable.

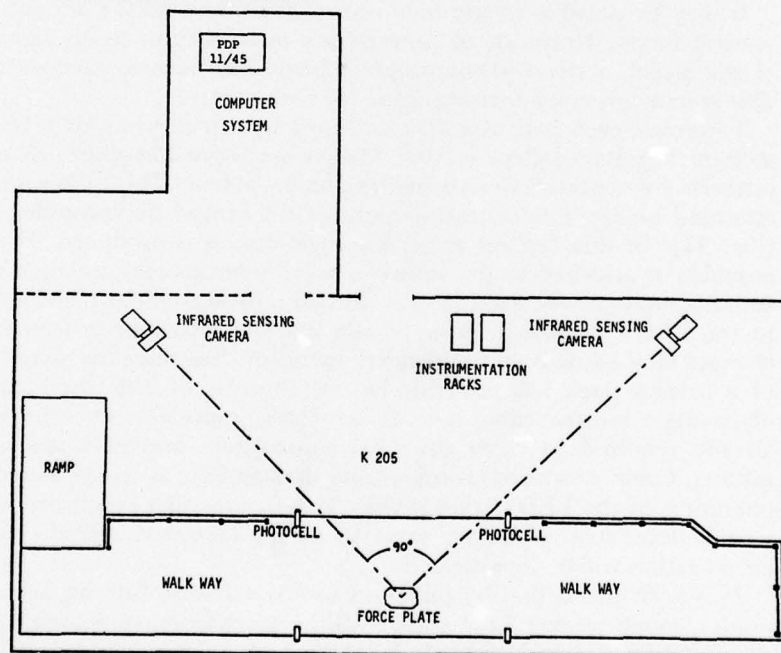


FIGURE 30. — Three-dimensional computer-based motion-study system laboratory layout.

3. Two LED's at each landmark target will be necessary to allow each of the individual anatomical landmarks to be monitored simultaneously by both cameras. The two LED's of each pair must be mounted as closely together as possible, and in such a manner that each is aimed as directly as possible at its corresponding camera.

4. The angular distribution of infrared radiation of the provided LED's is much too limited. This is largely due to the manufacturer's design. The LED is provided with a reflector designed to produce a more intense signal; consequently, the angle of radiation is small. Although intensity is important, a broader angular distribution is also necessary because the orientation of this light source with respect to the cameras continuously changes during a gait cycle.

5. Although optical synchronization is functional, it is not reliable when LED intensity is not sufficient.

Most of the above problems were significantly reduced when new LED's were acquired: these have an output with extremely broad angular distribution, and provide a considerable increase in the incident light intensity.

It may be possible to use only one of these new LED's per anatomical target. However, to prevent any possibility of losing sight of the signal, a two-LED-per-target scheme has been worked out. This scheme provides a strong signal for each camera.

To mount each pair of LED's, a 3-inch by 1-inch piece of 1/16-inch-thick polypropylene is used. Hinges are formed at appropriate intervals by repeated flexing of the polypropylene. The LED's are mounted on the two central sections of the hinged polypropylene (Fig. 31). In this fashion a variable-angle mount is produced. The assembly is attached to the subject's skin by means of double-stick adhesive tape on the outside tabs. Initially, power will be provided to the LED's through a cable from a line powered source. Design changes may allow battery powered operation, but since the weight of a battery pack will probably be on the order of 2 lb, the logic of having a patient carry it is questionable, especially since he is already required to carry the LED control unit and EMG transmitters. Cable synchronization will be used as long as line powered operation of the LED's is necessary. This insures that synchronization is never lost. However, ways to insure adequate optical synchronization will be investigated.

It is anticipated that by judicious use of software filtering techniques, much weaker LED signals will be acceptable, thus opening the possibility of using a single LED per target. This would significantly reduce the bulk and weight of the LED mounting fixture and simplify mounting procedures.



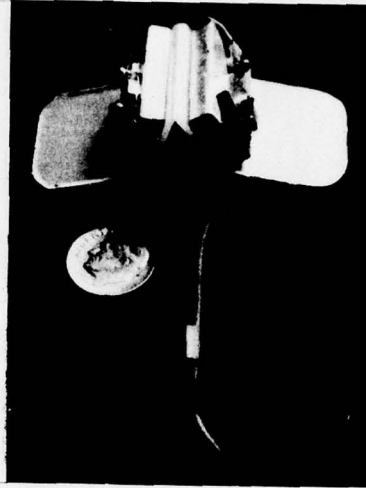


FIGURE 31. — Hinged polypropylene mounts for two light-emitting diodes. The LED's are visible as small spherical projections.

With regard to computer programing, the analysis already developed for the strobe system will be exactly applicable to the automated system. The difference between the two techniques is manifested entirely in the data-entry methods. In the strobe system this is a manual process, and in the automated system all data enter the computer directly without operator intervention. Thus the additional programing effort involves routines that control data acquisition, interpretation, and storage. To a large degree this has been accomplished, with only refinements necessary to insure faultless operation for simultaneous synchronous acquisition of Selspot, forceplate, EMG, and footswitch information. Once the data are filed in memory, the analysis and the generation and display of results are identical for strobe or Selspot systems, and are operational software at this time.

Kinematic data can be viewed within minutes after a run. A computer-generated stick-figure representing two LED's mounted on a subject's body is shown in Figure 32. Such output is a check on the validity of an experiment. If problems are indicated, the experiment can be repeated while the subject is still in the laboratory.

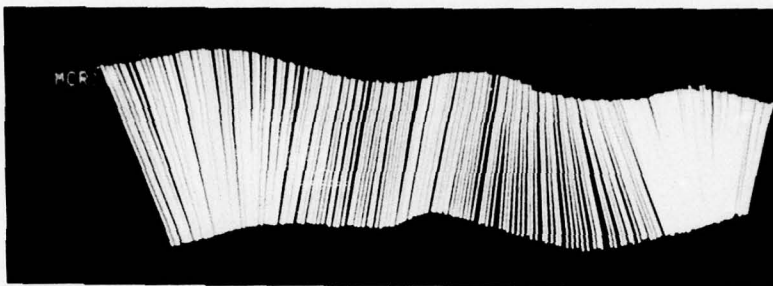


FIGURE 32. — Computer-generated stick figure progression representing two LED's, one on the left pelvis, and the other at the knee of a normal subject during fast level walking. The sample rate is approximately 150 Hz.

**Conclusions.** There is no doubt, at this point, that the automated system will be functional. In certain respects, such as encumbrance of the subject, this system is not as good as the strobe system, but the ability to provide results in minutes, as compared to weeks, far out-weighs the shortcomings.

#### Applications of Motion Analysis in Orthotics and Prosthetics

##### *1. Comparison of Implanted Electrical Stimulation (Neuromuscular Assist) to Five Other Methods of Treating the Equinovarus Foot in the Hemiplegic Adult*

Seven patients have been implanted with the NMA (Fig. 33). The original protocol suggested using a general anaesthetic for implantation. In view of past experience with surgery on patients of this type, the procedure was attempted with local anaesthesia and found to be reasonable. Several advantages were noted, as follows:

1. No recovery period from anaesthesia was needed;
2. Good feedback existed from the patient to warn of any undue pressure on the peroneal nerve; and
3. Cooperation of the patient in evaluating the interaction of his voluntary control with the functioning of the stimulator was possible.

Five of the seven patients still have their devices implanted. Two have been removed. One patient required a below-knee amputation of the opposite leg 3½ yr post implantation because of atherosclerosis. An above-knee amputation was required about 7 months later on the implanted leg. The implant continued to function well until surgical removal. Another patient was implanted with the

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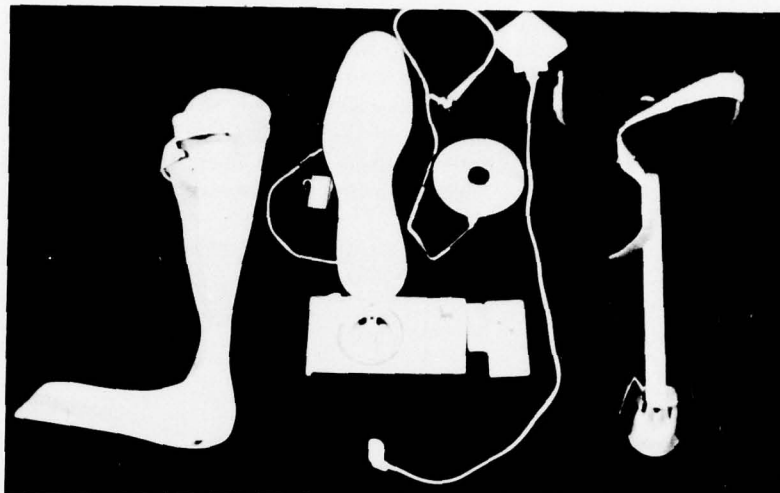


FIGURE 33a. — The NMA is in the center. The Engen AFO is on the left and the VAPC Clip is on the right.

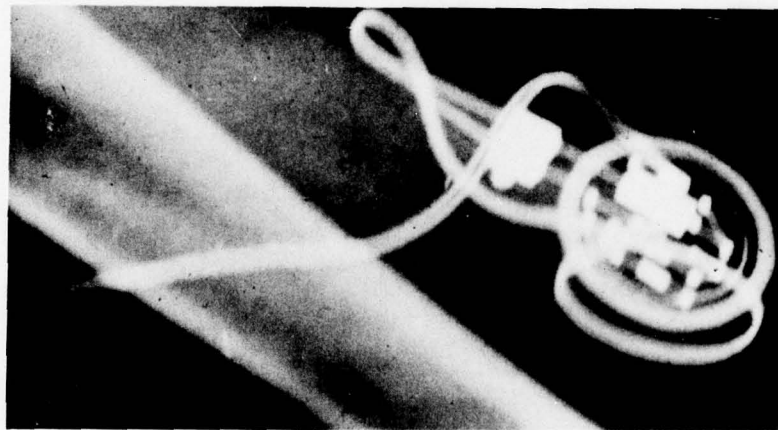


FIGURE 33b. — X-ray of implanted NMA.



NMA 1.4 yr post cerebral aneurysm repair. She had been stable prior to the implant. Following implantation, she continued to improve until she had regained complete voluntary control over the stroke-affected foot. She then asked to have the device removed because she feared possible future damage to the peroneal nerve. She was asked to go without the brace for 3 months and then was re-evaluated. The improvement in function remained and the im-

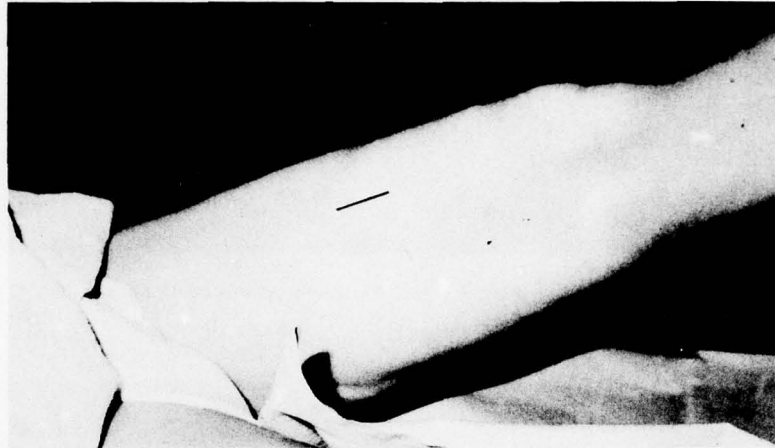


FIGURE 34a. — Line showing area of thigh incision on medial thigh. Actual incision was too cosmetic to show in photograph.

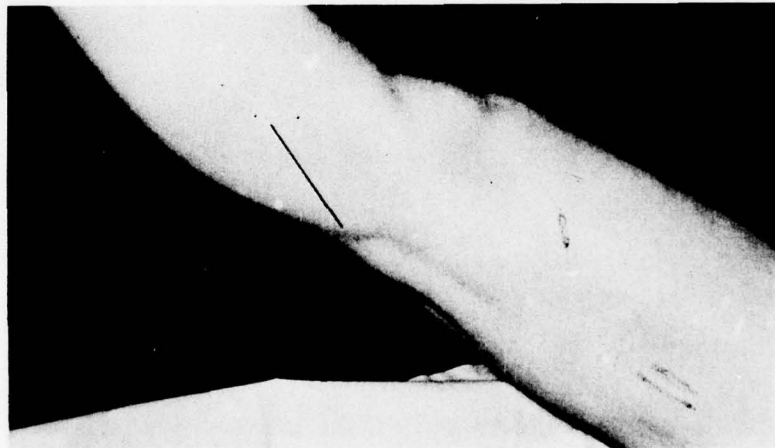


FIGURE 34b. — Line showing area of incision in lateral leg over peroneal nerve.

plant was then removed under local anaesthesia (Fig. 34). Tissue had grown into the Dacron mesh providing a very secure fixation. From this experience, it is our recommendation that any implant with the likelihood of requiring repeated re-insertion should not

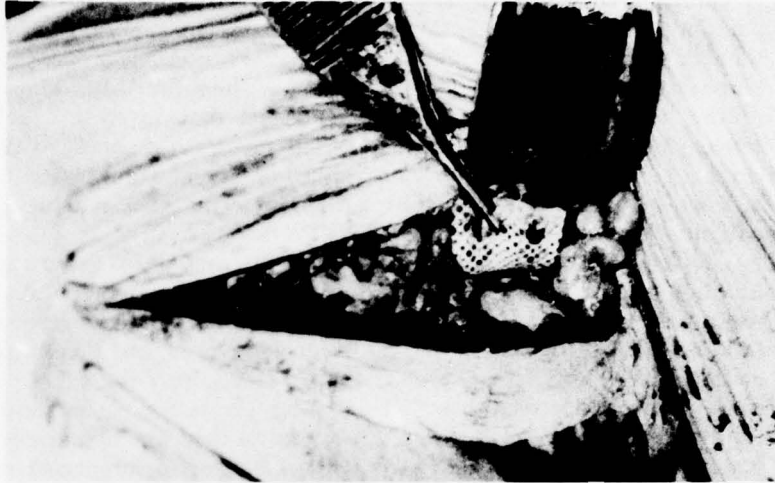


FIGURE 34c. — The electrode is partially removed showing the smooth gray membrane around the apparently normal nerve.

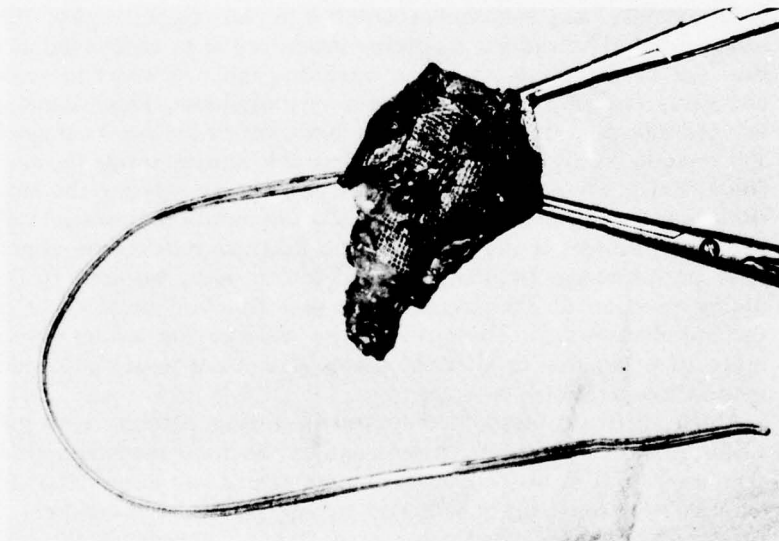


FIGURE 34d. — Hip portion immediately post removal. Note the ingrowth of tissue.

have a total Dacron covering. A few Dacron tabs should be sufficient for initial anchoring prior to the establishment of the connective tissue capsule.

There have been no infections and no failures of the implanted portion of the equipment. One implant failed to function at the time of initial insertion and a spare was substituted. The defective unit was returned to Medtronic, Inc. We have had numerous failures of the external equipment; foot switches, foot transmitters, belt transmitters, and antennae have all broken at various times. At the current state of the hardware, inspection of components is needed at least at 2 month intervals to maintain good function in an active patient.

The Foot Contact Laboratory was constructed to quantitate function of the various braces, since the Strobe System required too much time to allow the large number of determinations desired. Detailed analysis of the data is not yet completed, but 6 patients have expressed strong preference for the NMA over the other devices. One patient demonstrated excessive eversion post implantation and had difficulty walking safely due to this. She had demonstrated some valgus instability of her ankle prior to surgery. A re-implantation leaving out some peroneal fibers was suggested to her but she has not as yet decided to have this done. Some other patients initially demonstrated more than optimal ankle valgus but with exercise and subsequent anterior tibialis hypertrophy, this disappeared. The routine operating procedure is to always balance the foot in slight valgus on the operating table in order to avoid any varus since even a slight varus is very disabling. This balancing was initially done by separating the branches of the peroneal nerve and including only those that gave desirable motion inside the electrode. Balance was achieved in later patients by rotating the electrode on the entire nerve until satisfactory motion was achieved. Another problem is the effect of the postural reflexes on stimulator performance. Implantation and testing must be done in the supine position at the present time, but function must occur in the upright position. These difficulties indicate the strong desirability of being able to alter the varus-valgus balance of the system without reoperation.

Much difficulty was encountered in fitting patients with the FEPB (external electronic brace) and in teaching them and their families to put it on properly. In view of this, we doubt that the external electronic brace will ever be useful for large numbers of patients but feel it is valuable as a training device for the hospitalized patient where trained personnel can closely supervise its



use. The VAPC Clip, the Engen AFO, and the double upright orthoses presented no major problems.

We are currently evaluating the automated gait laboratory data on our seven patients even though we have not reached the goal of ten. The cooperative study (of which the implant portion of this project was once a part) is completed (4). The Medtronic Company, Inc., is no longer interested in pursuing the device at this time, but has agreed to provide us with materials necessary to complete our ten implants and to repair existing braces as needed. Our plan is to complete the analysis of our present patients and to continue implants during the analysis period as suitable subjects become available.

## *2. Stimulation of the Paralyzed Hip to Return Functional Use*

Electrodes have been implanted in the iliopsoas on one hemiplegic patient obtaining sufficient force to flex the hip. The patient was placed on an electrical exercise program. His spasticity markedly decreased, and his gait improved. After removal of the electrodes, the spasticity slowly returned. The rectus femoris of another patient was implanted. This patient was an above-elbow amputee with a below-knee amputation on the same side. He was wheelchair bound due to a 60 deg flexion contracture. The rectus femoris was implanted with 3 percutaneous electrodes and he was placed on an

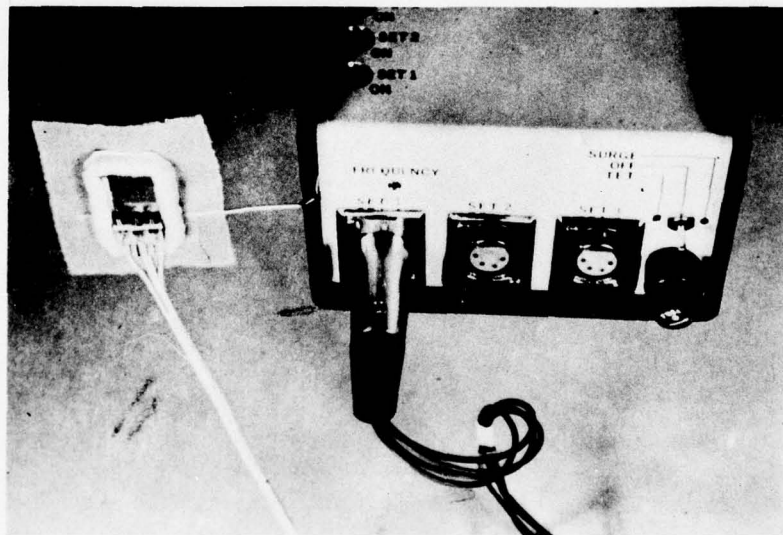


FIGURE 35a. — Stimulator and connector.

exercise program. There was some improvement in the reduction of the contracture to about 45 deg but there was marked improvement in quadriceps strength and the patient was able to walk without assistance.

An exercise stimulator to allow simultaneous activation of 3 electrodes was constructed. A new soft electrode connector to provide protection to the percutaneous electrodes in the groin area was devised. The stimulator, connector, and a set of implanted electrodes are shown in Figure 35.

A Brown-Séquard patient, who is currently about 1 yr post injury and is unable to walk, has expressed interest in our project. We plan to continue the project with him and other patients as they become available. A protocol for evaluating the effect of the electrical exercise has been established utilizing Cybex. We will continue the investigation of the muscles around the hip including the gluteus medius and gluteus maximus.

### *3. Development of Femoral Shaft Fracture Cast Brace and Manual*

Initiation of this portion of the project has been postponed since a major portion was under Dr. Albert Burstein. He has transferred from Cleveland to the Hospital for Special Surgery, New York City, New York.

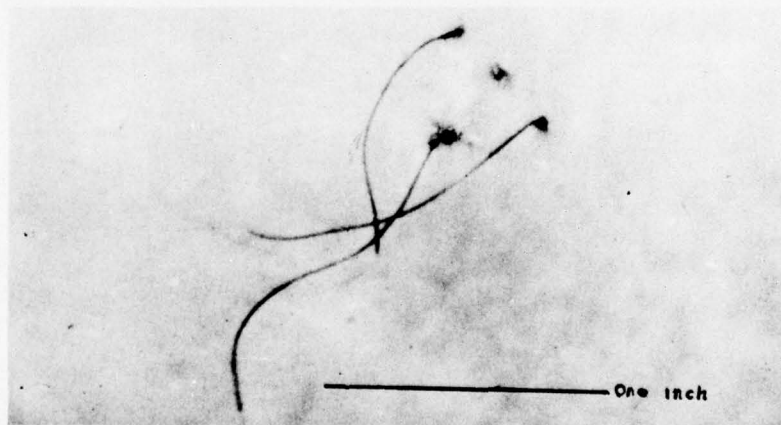


FIGURE 35b. — Percutaneous microelectrodes in place in skin. They are shown at about twice actual size.

**Collaborative Research**

**1. *In Vivo Loading on Hip Joint Replacements***

The telemetry receiving equipment has been constructed and installed in the Motion Study Laboratory to allow receiving of data from the implanted instrumented hips. No device has yet been implanted but we anticipate the eventual successful completion of this project. (See pages 193-194 in this issue.)

**2. *In Vivo Loading on Knee Joint Replacements***

This project uses the same telemetry equipment as the hip. An extension of the project has been submitted and eventual successful completion is anticipated. (See pages 193-194 in this issue.)

**3. *Investigation of the Response of the Righting Mechanism to Small Perturbations in Scoliotic Versus Normal Individuals***

This project is not being pursued at the present time. Scoliosis studies are being done pre and post fusion, to evaluate the effect of fusion on gait.

**Effects of Neuromuscular Diseases, Joint Disease, Surgery, Drugs, and Exercise on Body Motion**

The Foot Contact Laboratory is used on a regular basis to provide direct clinical information to the physician concerning his patient's gait. The evaluation is requested by the physician in the same way as electromyography or nerve conduction studies are requested. A large body of data documenting the effects of many variables on gait is being built. At present, these studies are being done in conjunction with evaluation with the Rancho Los Amigos Gait Analyzer in order to obtain a comparative evaluation.

***Other Related Work Accomplished***

The orthosis comparison study required an objective measure of orthosis performance. The strobe system was considered too cumbersome, and the automated 3-D system was not anticipated to be functional for some time. It was decided that a foot-to-floor contact analysis would be adequate.

In a search of the literature, it was soon realized that no suitable normal data base information existed for foot contact measurements. Therefore a significant effort was expended in establishing such a data base.

A completely automated foot contact analysis system was designed and constructed at the beginning of this reporting period.



This system is capable of providing temporal component measurements immediately following a run. A block diagram is shown in Figure 36.

Two normal studies were performed. One involved 51 male and female subjects walking at normal speeds only, and the other involved 14 male and female subjects each walking at a broad range of speeds from about 0.2 m/sec to as fast as each could reasonably walk. The data resulting from the larger study were normalized with respect to cycle duration and subjected to a linear multiple regression analysis in order to determine the equations that best predict the stance, swing, double support, heel, foot flat, and forefoot phase percentages. The independent variables included in this analysis were age, height, weight, speed, and cycle duration. The resulting equations were:

$$\text{Stance (\%)} = 75.63 + (.043 \times W) - (8.04 \times S) - (3.79 \times C) \quad [1]$$

$$\text{Swing (\%)} = 24.41 - (.043 \times W) + (8.06 \times S) + (3.73 \times C) \quad [2]$$

$$\text{Double support (\%)} = 25.83 + (.043 \times W) - (8.16 \times S) - (3.80 \times C) \quad [3]$$

$$\text{Foot flat (\%)} = 50.26 + (.066 \times W) - (14.78 \times S) \quad [4]$$

$$\text{Forefoot (\%)} = 25.56 + (4.98 \times S) - (10.64 \times C) \quad [5]$$

$$\text{Heel (\%)} = 1.14 + (6.51 \times C) \quad [6]$$

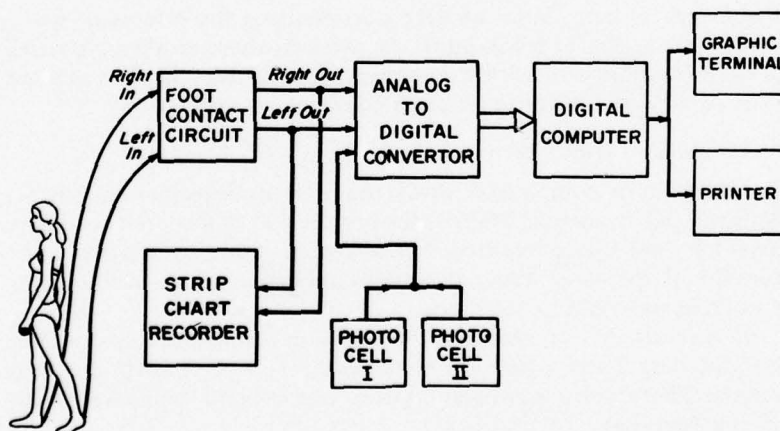


FIGURE 36. — Block diagram of foot-to-floor contact analysis system.

# Other VA Research Programs

where W, S, and C correspond to weight in Kg, speed in m/sec, and cycle duration in sec, respectively. Note that none of the phase measurements are related to either height or age. Equations [5] and [6] for forefoot and heel are not considered to be reliable outside of the range of normal speeds, as they account for only 12 percent of the variability in these parameters.

The smaller study of 14 subjects suggests that the stance, swing, double support, and foot flat equations are valid for all speeds of 0.6 m/sec or greater. Below that speed equations [1] through [4] do not hold. This smaller study also showed that the heel and forefoot phase percentages are essentially constants of 8.5 percent and 20 percent of the gait cycle, respectively, over the entire measurable range of speeds. It also provided equations for predicting stance, swing, double support, and foot flat percentages for speeds between 0.2 and 0.6 m/sec:

$$\text{Stance (\%)} = 78.73 - (19.08 \times S) \quad [7]$$

$$\text{Swing (\%)} = 21.38 + (19.08 \times S) \quad [8]$$

$$\text{Double support (\%)} = 28.84 - (19.48 \times S) \quad [9]$$

$$\text{Foot flat (\%)} = 47.85 - (12.41 \times S) \quad [10]$$

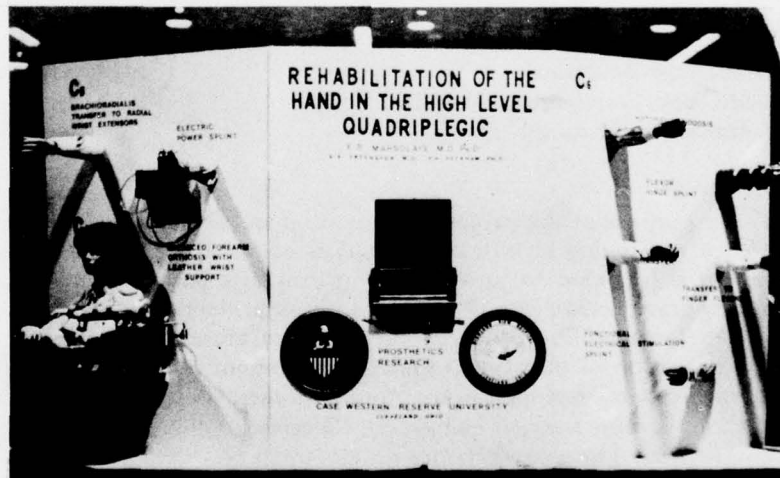


FIGURE 37. — Laboratory exhibit.

where  $S$  is the speed in m/sec. The methodology of this study was such that only the relationships between phase percentages and speed are meaningful.

Another special project of the laboratory was an exhibit entitled "Rehabilitation of the Hand in the High Level Quadriplegic" which was presented to the American Academy of Orthopaedic Surgery at the 1977 meeting in Las Vegas, Nevada (Fig. 37). The project was done in conjunction with Dr. A. A. Freehafer and Dr. P. H. Peckham. It consisted of moving prosthetic electric hands depicting various surgical and non-surgical approaches used to improve function in the quadriplegic hand. The exhibit was well received.

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**Patient Evaluation of a Functional Electrical Stimulation  
Hand Orthosis  
VA Hospital  
10701 East Boulevard  
Wade Park, Cleveland, Ohio 44106  
P. Hunter Peckham, Ph. D.**

#### **Introduction**

The purpose of this project is to develop and evaluate an orthotic system employing electrical stimulation of paralyzed muscle. This system is intended to provide C-5 quadriplegic patients with controlled grasp and release of the hand, through electrical stimulation of the forearm finger flexor and extensor muscles, respectively. The operation of the system under development is based on a prototype system developed in the Applied Neural Control Laboratory at Case Western Reserve University, Cleveland, Ohio, under H.E.W. sponsorship. The system under development is a miniaturized version of the prototype version and is designed to be easily donned and carried.



#### Operation of the System

Control of hand function is achieved in the following manner. *Movement of the head or shoulder in one plane is transduced and used as the proportional control input for governing the strength of contraction.* Movement in one direction from a neutral position activates the finger flexor muscles; movement in the opposite direction activates finger extension.

External stability provided by an orthosis is necessary to insure proper motion in the hand. A polypropylene orthosis, developed earlier, provides stability to the wrist or thumb, and finger rings are used to stabilize the interphalangeal joints.

Proportional control of contractile strength is achieved through both recruitment (activation of previously inactive fibers) and summation (addition of active responses). These are achieved by pulse width modulation and interpulse interval modulation, respectively, in the stimulation scheme.

Chronically in-dwelling percutaneous coiled wires are utilized for the active electrodes. For the finger flexor muscles, three electrodes are implanted into physically separate areas of the flexor digitorum superficialis or profundus. These electrodes are activated sequentially, 120 deg out of phase. For the finger extensor, a single electrode is implanted into the extensor digitorum communis.

Movement of the proportional controller, performed by the patient, controls the strength of contraction through a preset algorithm. This algorithm relates the control voltage to the output stimulus pulse width and stimulus frequency applied to each electrode set. Briefly, a demand for increased contraction strength is answered by increasing the pulse width(s) with the stimulus frequency held constant until a predetermined control level is reached. Further demands for increased strength are met by increasing the stimulus frequency while holding the pulse width fixed at its maximum values.

The system being developed incorporates control logic which simplifies the patient's control task. The two functions provided by the control logic are to enable him (i) to turn the system on and off which specifies his zero reference position at any point in time, and (ii) to "hold" a desired control level (stimulus output) independent of his shoulder position. Previous studies have demonstrated that these control functions are necessary if the high level quadriplegics are to operate this type of system. This is principally because postural changes, which occur in performing various tasks, would otherwise require the patient to exert extensive, continuous, conscious control. In the system under development, these functions are activated by a two-level processed myoelectric signal,

obtained from a site with some remaining voluntary activity. Exceeding a lower level with the myoelectric activity activates the "hold" function; exceeding the upper level activates the "on/off" function. Signal acquisition for the myoelectric switch is through a chronically indwelling bifilar coil wire recording-type electrode.

#### Device Design and Fabrication

The hardware implementation of the system functions was developed with the constraints of (i) small size and light weight, to allow the unit to be carried by the patient, (ii) low power consumption, to permit infrequent battery recharging or replacement, (iii) ease of attachment to patient transducers and electrodes, and (iv) a maximum degree of patient safety in the event of a circuit failure.

The various circuit functions are built on three miniature printed circuit boards. These appear as boards #1, #2, and #3 in the block diagram of the basic system (Figure 38). The use of printed circuits enables a high component density to be achieved while still maintaining a reliable and easily reproduced device. The circuit density is further enhanced by the elimination of internal switches and potentiometers: the exact parameters of stimulation, which vary from patient to patient, will be set by smaller fixed-value resistors and jumpers. The three boards (each approximately 3 × 5 inches) are stacked vertically over one another; interconnection of the boards

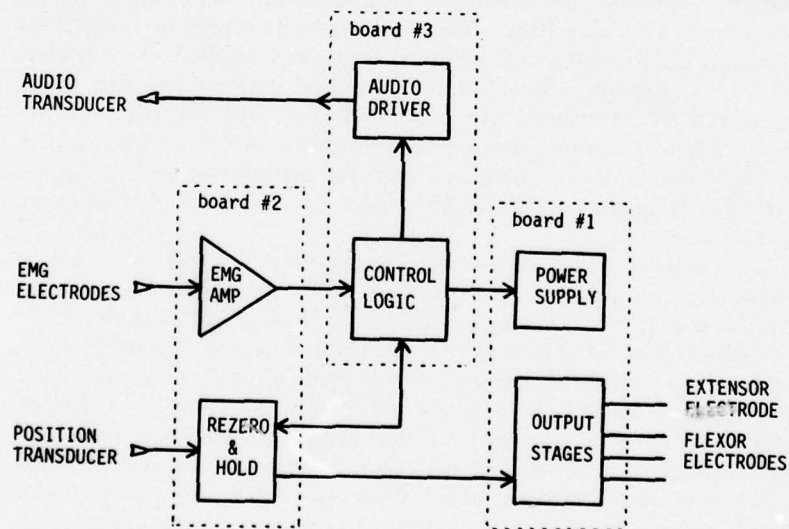


FIGURE 38. — Block diagram of electrical stimulation hand orthosis.

is through simple strip connectors at the ends. The complexity of this interconnection was minimized to avoid future contact problems as the units are used and serviced.

The objective of minimal power consumption is realized through two basic approaches: 1. each of the individual circuit functions is implemented with low-current components and designs, and 2. during the OFF state, power is supplied only to the EMG amplifier and part of the control logic. Thus, when the system is in the OFF state (which is true much of the time) only about 20 percent of system circuitry is supplied with power. The power supply receives its power up or down commands from that portion of the control logic which is always powered. The power to the unit as a whole is turned on by the act of attaching the single connector going to the patient electrodes and transducers. This eliminates the need for a separate on-off switch.

Two non-rechargeable mercury batteries are expected to operate the system for about two months of service. This was determined to be more desirable than using rechargeable batteries of comparable size.

Emphasis was placed on safety considerations in the design of the stimulator. Electrical isolation between the EMG amplifier and the stimulator section insures that no current can flow to or from the indwelling EMG electrodes, even during a system failure. In the stimulator section, four identical output stages are used. Each stage generates a controlled current pulse which is capacitively coupled to the patient's stimulating electrode (cathode) to produce a net biphasic current flow. The stimulator outputs are monitored by a protection circuit whose function is to shut down the system should the stimulating pulse width or rate become excessive: this redundant circuit operates in the event of a device failure, to prevent damage to the electrode, and/or muscle tissue injury.

A laboratory version of the stimulator has been built and tested. This larger device has been used to verify the design and function of the various circuits which, in turn, were designed into the miniature system. The laboratory stimulator has panel-mounted potentiometers and switches which allow the various stimulation parameters to be varied. Predetermined parameters for a patient's stimulator will be set into the laboratory unit, his usage of the system observed, and any necessary parameter modifications made. These parameters will then be fixed into the miniature unit for that patient. Later changes, if necessary, can be made by repeating the process. Completed, in addition to the laboratory device, is board #1 which is currently being etched commercially. This board is the most complex of the three, and contains largely analog circuit



functions. Boards #2 and #3 are now being laid out; when completed they will also be etched and assembled.

**Patient Evaluation**

Two C-5 quadriplegic patients have been involved in these studies in the period reported upon here. These patients, who have used the C.W.R.U. prototype system in previous work, have been involved in two aspects of development of the present system. First, they have worked with the laboratory stimulator to insure its proper operation. Specifically, studies with these patients have allowed the measurement of interaction between the electromyographic signal and the output stimulus, and determination of the necessity for feedback of the control state to the patient. Secondly, these changes have been incorporated, whenever possible, into the prototype system to determine, preliminarily, the efficacy of the modification. The patients involved in this stage of evaluation are presently fitted with the modified prototype systems, and they will be the first to receive new systems, which are expected to be completed in the next period.

**Ultralight Below-Knee Prosthesis  
Rehabilitation Engineering Center  
Moss Rehabilitation Hospital  
12th Street and Tabor Road  
Philadelphia, Pennsylvania 19141  
A. Bennett Wilson, Jr.**

The goal of a 6-month contract with the Veterans Administration (contract ended April 30, 1977) was to demonstrate the feasibility of an ultralight below-knee prosthesis. Practical techniques for fabrication of below-knee prostheses that weigh 60 percent less, size-for-size, than the comparable conventional PTB type were developed and presented in an instruction manual.

Fabrication is by molding sheet polypropylene. Although the fabrication time is about the same as that required by the more conventional techniques, labor can be reduced after one or more manufacturers make available either permanent molds, or temporary foot sections, for use in molding the foot-ankle part of the prosthesis.

Although designed with problems of the geriatric patient in mind, the ultralight below-knee prosthesis has been received extremely well by BK patients of all ages and all categories. An addi-

tional advantage of weight reduction is a reduction in the suspension problem. The current technique of fitting does not require any suspension other than the supracondylar tabs that are an integral part of the socket.

**Orthopedic Implant Device Retrieval and Analysis**

**VA Hospital**

**New Orleans, Louisiana 70146**

**Allan M. Weinstein, Ph. D.**

All orthopedic implant procedures are followed on a prospective basis, and all implants that are removed during the normal and routine medical care of patients are collected. Patients receiving orthopedic implants are followed from the time of insertion until removal (if removed). A photographic record of each implant is made in vitro just prior to implantation, and in vivo immediately post-implantation. Also, a culture of the tissue area at the implantation site is performed at implantation and removal.

The essential components of our retrieval and analysis program are outlined as follows.

1. Implantation
  - a. Case history
  - b. Roentgenogram review
  - c. Culture implantation area
  - d. Record of implant
2. Recovery of Implant
  - a. Case history review
  - b. Roentgenogram review
  - c. Tissue sample adjacent to implant
  - d. Culture adjacent to implant
  - e. Photographic record of implant
3. Examination of Implant
  - a. Macroscopic
  - b. Microscopic
  - c. Properties
  - d. Chemistry
4. Examination of Tissue
  - a. Histology
  - b. Identification of culturable organisms, if any
  - c. Quantitative determination of foreign bodies if present

5. Correlation
  - a. Reason for removal
  - b. Implant performance
    - (i) Clinical
    - (ii) Engineering
  - c. Operative procedure
    - (i) Implant choice
    - (ii) Technique
  - d. Diagnosis
  - e. Histology
  - f. Radiographic changes
  - g. Materials characteristics

We are currently using data forms essentially identical to those being developed within ASTM F-4 and described in an ASTM draft document entitled "Recommended Practice for the Retrieval and Analysis of Metallic Orthopaedic Implants."

There are currently 23 patients in the study; 13 of them prospective and 10 retrospective. (One of the prospective implants has been retrieved.) The devices involved cover the standard armamentarium of the orthopedist, and are shown in Table 3.

A typical summary of the clinical and metallurgical analyses performed for each case is illustrated, from an actual case, in Table 4 and Table 5.

TABLE 3. — *Devices Involved*

	Prospective	Retrospective
Jewett nail plate	6	1
Screws or pins	—	4
Intramedullary rods	—	1
Joint endoprotheses	4	2
Hip nail	1	—
Bone plate	2	2

TABLE 4. — *Summary of Case History Review*

Length of time implanted	1 month
Implant type	Jewett nail
Patient sex and age	Male — 76
Diagnosis at insertion	Fracture; right hip
Reasons for removal	Pain, infection, instability



# Other VA Research Programs

TABLE 5. — Summary of Metallurgical Examination

	Number of components: 5				
	Nail-plate	Screw #1	Screw #2	Screw #3	Screw #4
Galling	—	—	—	—	—
Burnishing	mild	—	—	—	—
Change of shape	—	—	—	—	—
Mechanical damage	severe	—	—	moderate	—
Microporosity	—	—	—	—	—
Corrosion	fretting	crevice pitting	crevice	crevice pitting	crevice
Chemical composition	316L <sup>a</sup>	—	—	—	—
Knoop hardness test (microhardness)	nail 220 plate 170	380	340	390	390
Hardness (R <sub>B</sub> "B") (Rockwell method)	80	—	—	—	—
Grain size	nail 6.5 plate 7.5	—	—	7	—
Inclusion content	nail 2-heavy plate 1-medium				

<sup>a</sup> Stainless steel, A.I.S.I. Type 316L, salt-water-resistant.

The microstructure of this particular implant is shown in Figure 39.

In order to evaluate the mechanical properties of these implants, a microtensile specimen is fabricated from each implant when possible. A typical sample is shown in Figure 40. This sample will facilitate a determination of yield strength, tensile strength, percent elongation and percent reduction in area. These data can then be correlated with the hardness and microstructural data and compared to the properties determined from testing larger samples of the same materials in the same metallurgical conditions. To date,

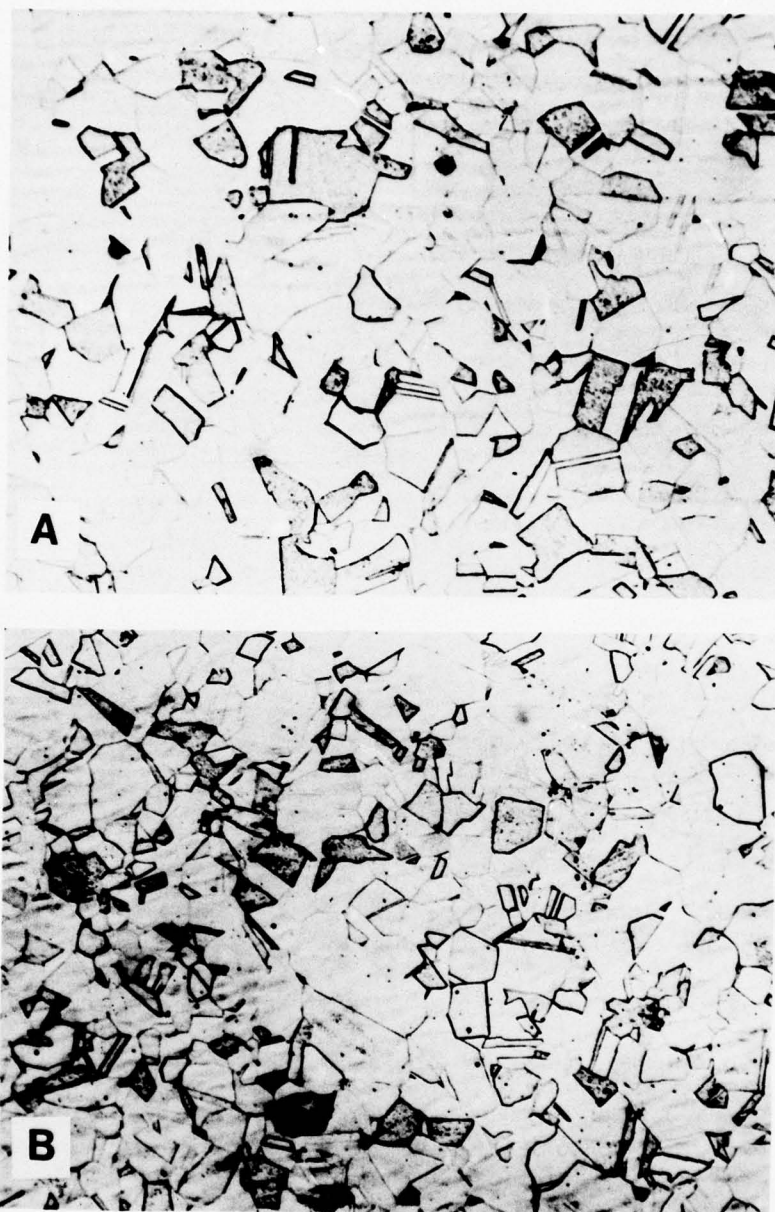


FIGURE 39. — Representative microstructure of the plate portion of the device: (a) longitudinal and (b) transverse sections. Magnification 250x.

#### Other VA Research Programs

no correlations of data have as yet been attempted, as a sufficient number of implants has not been retrieved.

#### Toward a Nationwide Retrieval Program

As part of the project, the feasibility of extending this study to a nationwide retrieval program for the entire VA system is being investigated. Collaborative arrangements are being made with other VA hospitals and engineering centers to expand the retrieval program. The VA Hospital, Columbia, South Carolina, is retrieving implants and forwarding them to the Tulane University Biomaterials Laboratory for analysis. The VA hospital in Irvine, California, has agreed to participate. In addition, the Utah Biomedical Test Laboratory and the University of Pennsylvania have each expressed interest in establishing regional implant analysis locations. Their respective VA hospitals (Salt Lake City and Philadelphia) are also interested in this study.

The engineering centers would obtain implants from a certain geographic area adjacent to each center. All data would ultimately be correlated by one group: in fact, it is envisioned that if one center has a unique expertise, then that center would be responsible for all implant evaluations involving that expertise. It should be pointed out that it appears that establishing an engineering

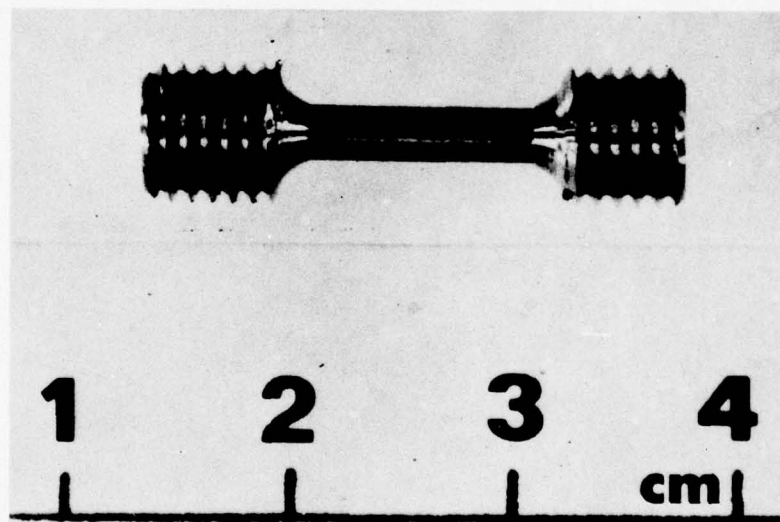


FIGURE 40. — Typical microtensile specimen machined from the plate portion to determine mechanical properties.



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center at each VA hospital is not necessary, as the implant output is insufficient. It will be quite feasible for one engineering laboratory to handle the output of multiple hospitals.

Goals for the coming year are —

1. To continue the retrieval and analysis program at the VA hospitals in New Orleans, Louisiana, and Columbia, South Carolina;
2. To expand the southern regional collections to other local hospitals such as Atlanta, Gulfport, Augusta, etc.; and
3. To establish two other engineering centers, one at the Utah Biomedical Test Laboratory, and the other at the University of Pennsylvania.

**Evaluation of Electrical Techniques for Stimulation of Hard  
Tissue Growth**

**VA Hospital**

**Irving Avenue and University Place**

**Syracuse, New York 13210**

**Robert O. Becker, M.D., J. A. Spadaro, Ph. D., and**

**A. A. Marino, Ph. D.**

No progress report was submitted by this contractor for this report period. A full report will be in the next issue.

## SENSORY AIDS

*Edited by*

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**Research on Audible Outputs of Reading Machines for the Blind**  
**Haskins Laboratories, Inc.**

270 Crown Street  
New Haven, Connecticut 06510

Franklin S. Cooper, Ph. D., Jane H. Gaitenby, Frances Ingemann,  
Ph. D., Andrea Levitt, Ignatius G. Mattingly, Ph. D., Patrick W.  
Nye, Ph. D., and Linda Shockey, Ph. D.

### **Introduction**

The objective of the research reported below is the improvement of the intelligibility and naturalness of speech produced by an automatic synthesis-by-rule system. Such a system would be a major component of a reading machine for the blind. Work is reported below on the development and testing of a synthesis program and of rules for synthesis, and on phonetic investigations in support of rule development.

### **Development of Rules with FOVE Program**

There has been further development and testing of rules for use with FOVE, the synthesis-by-rule program for the DDP-224 computer that calculates parameter values to drive the OVE III hardware synthesizer. A set of rules developed during 1976 has been subjectively tested. The subjects, students and staff at the University of Kansas, were asked to transcribe synthetic utterances which included both isolated words and connected sentences. The results can be compared with those from similar tests of the 1974 FOVE rules: intelligibility of sounds in isolated words remained the same (84) percent; intelligibility of sounds in sentences improved from 83 percent to 86 percent; the sounds /b, t, d, θ, h, w, c, ɔ, a/

appeared to have improved but /ŋ, ʃ, ʒ, j/ were poorer.

Meanwhile, a further revision of the FOVE rules took place in early 1977: changes were made in the frequency values of velar stops and nasals, in the amplitude values of nasals and voiced stops, in the durations of stops, fricatives and affricates, and in the frequency and amplitude values of affricates, fricatives, and releases of final stops. Materials for subjective testing parallel to those used in testing the 1976 rules were prepared.

#### Research Synthesis-by-Rule

SYLSYN, the research synthesis-by-rule program for the PDP 11/45, has been expanded and improved. It now includes a software synthesizer consisting of a noise generator, a pitch generator, a vowel branch with five formants, and a nasal branch and consonant branch each having one formant and one antiformant. The part of the program that calculates articulatory influences and parameter values from a syllable-feature specification has been expanded so as to handle all the conventional manner classes (stops, fricatives, nasals, liquids, glides, and vowels). The logic of the program has been simplified somewhat, and its execution time has been reduced.

#### Temporal Variation and Speech Synthesis

A series of experiments investigating the temporal patterns of syllables has been carried out. In each of these experiments, a speaker repeated a certain syllable 30 times in the sentence frame, "She was seen on ——— Street by her mother." To lessen tempo variation, each utterance was prompted by a click from a metronome. Waveform measurements of various segmental durations were averaged across the 30 tokens. Data have now been collected for a number of syllables with nucleus [ey] and varying initial and final consonant and consonant clusters, uttered by three speakers; some comparable data has also been collected for the nucleus [I]. The general finding — to which there are various exceptions — is that the increment to the syllable duration produced by an initial consonant is relatively uniform across the various cluster contexts, whereas the duration of the acoustic segment conventionally associated with the consonant varies according to cluster context. For final consonants, the situation is more complicated; a cluster such as [nd], for example, lengthens the syllable to an extent that is not obviously predictable from the lengthening effects of simple final [n] and simple final [d].



#### Other Experiments on Duration

In an attempt to explore the importance of naturalness in duration, four semantically acceptable sentences and ten monosyllabic nonsense sentences were prepared in two versions. In one version the 1977 FOVE rules were used, and the durations of acoustic segments of each synthetic sentence were then modified to be equal to those in a natural utterance of the sentences; in the other version, the 1977 rules were used without modifying durations. Subjects were required to transcribe both modified and unmodified sentences. In the case of the semantically acceptable material, 79 percent of the words in the unmodified sentences and 86 percent of the words in the modified sentences were correctly transcribed; for the nonsense material, the corresponding results were 77 percent and 85 percent. However, the apparent advantage may have been a learning effect, since the unmodified sentences were always presented first.

Another study involved the manipulation of stop-closure duration in natural speech. In a pilot experiment, the utterance, "Uncle Tom took a long time telling the tale to two of the Thompsons" was recorded by two talkers. In these utterances the closure durations for [t] ranged from 20 to 80 ms. Using a computer program for waveform editing, three additional versions of each utterance were prepared, in which the [t] closures were adjusted to be uniformly 0, 30, and 100 ms, respectively. Five phonetically alert listeners judged both the originals and the 30-ms versions to be natural, the 100-ms versions to be unnatural and heavily stressed, and the 0-ms versions to be natural but very fast. This experiment suggests that closure durations are important cues to tempo. Inconsistency of tempo cues is probably a major deficiency of current synthesis-by-rule.

#### Segmental Cues

In order to obtain information about the interaction of steady-state frequency values and formant transitions, and their effect on stop consonant perception, a series of experiments has been recently carried out. It is expected that the results of these experiments will provide useful information for calculating the feature target values and their influence functions to be used in the syllable synthesis program.

A series of four vowels with a fixed  $F_1$  at 840 Hz and a fixed  $F_3$  at 270 Hz, but with a varying  $F_2$ , were constructed.  $F_2$  frequencies for the four vowels were 1200, 1400, 1680 and 2100 Hz, and all of these vowels were perceived as falling into the [a]-[æ] range in a

vowel identification test. While  $F_3$  was held constant at a flat 2700 Hz, the starting-point of the  $F_2$  transition was varied in ten 200-Hz steps from 850 to 2650 Hz, creating a [b]-[d]-[g] continuum for each of the four vowels. Nine subjects listened to randomized sequences of these continua, and their data revealed the [b]-[d] and [d]-[g] crossover points for each vowel. A new series of continua were then constructed around [b]-[d] crossover points. A five-step, 100-Hz-per-step,  $F_2$  range (with the [b]-[d] crossover  $F_2$  transition value as the central point) was exhaustively paired for each vowel with a seven-step  $F_3$  starting-point range from 2100-3300 in 200-Hz steps (with a level  $F_3$  transition starting at 2700 Hz as the central point). Twelve listeners were then asked to listen to a randomized sequence of each of the original [b]-[d]-[g] continua, with flat  $F_3$ , as well as the [b]-[d] crossover series, with both  $F_2$  and  $F_3$  varying.

The results of this experiment will provide useful information for calculating the effect on stop consonant perception of independently changing  $F_2$  and  $F_3$  transitions. For example, it has been found (just as in the early Haskins Playback experiments), that the higher the starting point of the  $F_2$  transition, the greater the number of [d] or [g] responses and the fewer the number of [b] responses. For an intermediate range of  $F_2$  starting points, raising the  $F_3$  starting point increases the number of [d] responses; lowering it increases the number of [b] and [g] responses. Information such as this can be incorporated into the syllable synthesis program to produce more intelligible speech.

#### Research and Development in the Field of Reading

##### Machines for the Blind

Mauch Laboratories, Inc.

3035 Dryden Road, Dayton, Ohio 45439

Hans A. Mauch and Glendon C. Smith

In a letter of July 21, 1977 to Mauch Laboratories, Mr. Glendon C. Smith, Senior Project Engineer of the Reading Machine Project, tendered his resignation from that organization to be effective September 30, 1977. This loss of a principal talent in the reading machine work caused the company to schedule withdrawal from the project after appropriate final documentation had been completed. A technical report dated October 5, 1977, "Final Report on Research and Development toward A High Performance Reading Machine for the Blind (Cognodictor)" comprising 121 text pages and a comprehensive set of drawings, has been submitted to the

#### **Other VA Research Programs**

Veterans Administration (VA). The VA is considering continuation of this project through publication of a Request for Proposals (RFP) by which means a follow-on contractor may be selected with the aim of carrying the work to a successful completion.

**Clinical Trials of Reading Machines for the Blind  
Central Rehabilitation Section for Visually Impaired and  
Blinded Veterans  
VA Hospital  
Hines, Illinois 60141  
John D. Malamazian and Harvey Lauer**

This ongoing, centrally directed project is concerned with the clinical evaluation of reading and other communication aids for the blind. During the current reporting period, the following work was done:

Mr. Lauer has rewritten portions of his proposal to evaluate the Kurzweil Reading Machine. The Kurzweil machine has a computer-controlled scanner, computer-assisted optical character recognition, and synthetic speech output. The first one purchased by the VA was delivered to VAH Hines, June 1, 1977. Kurzweil Computer Products personnel installed the machine and then instructed Mr. Harvey Lauer and other Hines staff in its operation. The machine was inspected by Mr. Lauer and Mr. Howard Freiburger of the Research Center for Prosthetics, New York. The instrument having essentially met its specifications, Mr. Lauer and others are currently working to gain skill in its use and are developing lesson plans and reading materials. Interest in the machine is such that several open house sessions are to be held for hospital staff and professionals who work with blind people.

Mr. Lauer began the evaluation of the Am-Bi-Chron Model LC, a speech compression module. The instrument is an accessory to be connected to Library of Congress cassette talking book player models C73 and C75. It uses the sound system and DC power supply of the players.

On February 24, Dr. Lawrence L. Scadden, researcher with Smith-Kettlewell Institute of Visual Sciences, San Francisco, California, visited the Hines Blind Rehabilitation Center. He conferred most helpfully with Mr. Leicester W. Farmer, Mr. Lauer, and other staff members regarding ongoing research efforts throughout the world. Plans were made for cooperation on the Kurzweil Project and other research.



Mr. Lauer presented the topic: "Reading Aids Research and Deployment" to a communications conference held at Hines May 4-6. It was attended by staff members who teach communications skills to blind people at VA facilities.

Mr. Leonard Mowinski (Blind Center staff member at Hines) continued to do most of the screening and teaching of reading aid use to veterans. Mr. Lauer and Mr. Mowinski shared the duties of lecturing and demonstrating the reading aids to guests.

**Clinical Study of Mobility Aids for the Blind  
Central Rehabilitation Section for Visually Impaired  
and Blinded Veterans**

**VA Hospital**

**Hines, Illinois 60141**

**John D. Malamazian and Leicester W. Farmer**

During this reporting period, two veterans received training and were issued electronic travel aids and three more veterans will be admitted for training prior to June 30, 1977.

Two light probes, the Bejed wrist model and the three-way amplifier model, were evaluated at Hines during February and March.

The wrist model is in a small plastic case containing transistors, electronic components mounted on a small circuit board powered by two hearing-aid batteries, and a capacitor. It is approximately the size of a wrist watch. It provides an audible signal to the user by means of a tiny earphone which plugs into the proximal side of the case. A semiflexible, light-conductive fiber optic probe plugs into the distal side of the case. The pitch of the tone emitted by the device is proportional to the intensity of the light. When the earphone is unplugged, the power is automatically turned off to save battery energy.

The three-way amplifier model is in a small plastic box  $3\frac{1}{2} \times 2\frac{1}{4} \times 1\frac{1}{4}$  inches in size, which makes it easy to carry. This model has a small amplifier and loudspeaker with a thumb wheel on-off volume-control switch. There are two jacks on top of the unit, one to accept a cord two feet long which has a sensor at the end of a ballpoint-pen-sized cylinder. The other jack can accommodate an earphone or a headset adapter cord (which can be used also with the wrist-model probe). When one of these output accessories is plugged in, the loudspeaker is automatically disconnected. This unit has been used effectively by blind switchboard operators and telephone receptionists to detect the light of telephone key sets or consoles.

#### Other VA Research Programs

The investigators found the three-way amplifier model light probe to be sensitive, compact, and well built, with good vocational potential as well as being useful in the home and elsewhere. They were not only impressed by the fact that the wrist model light probe was designed to be wrist-mounted, but also by its high degree of sensitivity and versatility. Like other probes on the market, it can be useful in many ways. In addition to detecting light sources such as lighting fixtures and those found on electrical appliances and electronic instruments, it can be used to check the liquid level in transparent containers, to test batteries with ordinary testing meters (both the kinds with lights to indicate the strength of battery charge as well as the ones with "needle" indicators), to differentiate among colors and identify light and dark clothing, to detect windows and open lighted doorways, to determine the proper floor in elevators with lighted buttons that go out when the desired floor is reached, and it can be useful in darkrooms where it helps the user to avoid ruining x-ray film.

The Bejed light probes are manufactured by members of Oregon Chapter No. 31, Telephone Pioneers of America, Portland, Oregon.

#### Glucose Analyzer Tested

From January to March, the Snipas Glucose Analyzer (Triformations Systems, Inc.) was tested and evaluated by the Blind Rehabilitation Center Orientation and Mobility staff and the Endocrinology/Diabetes Unit at VAH, Hines. The device has not been marketed, but has been distributed to selected agencies for field testing and evaluation. The purpose of the tests and evaluation is to determine the extent of potential use of the glucose analyzer, and to identify any possible limitations.

The Snipas Glucose Analyzer is a portable electronic device that measures  $7\frac{1}{4} \times 4\frac{1}{4} \times 3$  inches, and weighs approximately 1 lb. It is intended to be used by blind diabetics to determine the approximate percentage of glucose in their urine. It measures the shade of a test strip which has been dipped in a fresh urine specimen, and then generates a series of audible tones, the number of which indicates the shade of the test strip. A yellow strip (indicating 0 percent glucose) will cause it to produce one tone, and a dark green strip (indicating 2 percent or more glucose) will cause 5 tones. In-between shades generate 2 ( $\frac{1}{10}$  percent), three ( $\frac{1}{4}$  percent) and four ( $\frac{1}{2}$  percent) tones respectively.

The glucose analyzer must be calibrated prior to use, and cleaned to remove urine traces after use.

Hines is one of probably 13 blind rehabilitation agencies involved in the evaluation of the glucose analyzer. Data collected from the

participating agencies will be analyzed to determine whether certain factors contribute to success in using the device or restrict its usefulness for certain persons. The information submitted by the agencies will provide the manufacturer with data needed to determine whether modifications of the prototype are necessary.

Mr. Leicester W. Farmer was one of the participants at the workshop on Sensory Deficits and Sensory Aids jointly sponsored by RSA and VA, which was held March 23-25, 1977, at the Smith-Kettlewell Institute of Visual Sciences, Pacific Medical Center, in San Francisco, California. He was a discussant in the session addressing current status, future trends, and priorities in basic and applied research on sensory deficits and sensory aids. The purpose of the workshop was to develop clear and frank recommendations on the goals and priorities for sensory aid research for later inclusion in a major RSA/VA summary statement on the outlook (plans, programs, and budget) for future research and service delivery for the handicapped.

Also during this reporting period, Mr. Farmer submitted a manuscript to the editors (two members of AAWB) which will be one of 19 chapters in a textbook, the tentative title of which is "Orientation and Mobility for Visually Handicapped Persons: Development and Fundamental Principles." Mr. Farmer's chapter will consist of two topics entitled, "Various Types of Canes and Walking Aids", and "Electronic Travel Aids and Systems." The textbook will be published this year by the American Foundation for the Blind.

**Clinical Application Study of Reading and Mobility Aids  
for the Blind**

**Western Blind Rehabilitation Center  
VA Hospital**

**3801 Miranda Avenue, Palo Alto, California 94304**

**J. Kenneth Wiley, Gregory L. Goodrich, Ph. D., Richard R. Bennett,  
and Stanley Paul**

**Mobility Aids and Training**

During the current reporting period, the Western Blind Rehabilitation Center initiated a followup study of veterans who have received orientation and mobility training at that Center. The study was designed to obtain information for two purposes.

The first purpose resulted from findings of a previous research project on the utilization of ETA's (electronic travel aids) (Darling,



Goodrich, and Wiley 1977), which explored the travel patterns of veterans trained and issued ETA's by the WBRC. This study indicated differential employment of Laser Canes and Sonicguides, which may lead to more precise guidelines for matching a particular ETA with a particular user.

The same study also indicated that many ETA users employed the device for a relatively brief duration after returning to their home community. These veterans indicated that, while the ETA was initially useful for mobility purposes, its benefit was of a limited duration. Such results may suggest the need to provide ETA training and ETA's to some veterans with the explicit expectation that the aid may be returned (for re-issuance to another veteran) within 6 months to 1 year after ETA training. The results also suggest that such a procedure, even though of limited duration, could be of substantial benefit to selected veterans. Thus the present study was designed, in part, to assess the needs of veterans not receiving ETA training, in an attempt to estimate the number who would benefit from such a limited program.

A second purpose of the present followup is to provide evaluative information to the WBRC's orientation and mobility instructors. Such information was thought to be useful in assessing strengths and weaknesses of the current program so that necessary changes (if any) could be made. For example, the followup will provide verbal and photographic information about the home communities of a large number of veterans. Such information can then be used to select appropriate training areas for veterans, based on more detailed information than is currently available.

Currently, followup visits have already been made to 22 veterans who have received orientation and mobility training from the WBRC. During the remainder of the current fiscal year an additional 28 veterans will be visited. In the next fiscal year an additional 20 veterans will receive followup visits, and 30 veterans who have not received ETA training will also be visited to complete the present study. The total number of veterans for the followup study will be 100.

During this report period, one veteran received instruction with the Pathsounder and a second veteran received instruction with a Sonicguide. Both veterans were issued these respective aids.

#### **Reading Aids and Training**

A preliminary evaluation was initiated of the intelligibility of the output of the Votrax voice as programed by Mauch Laboratories. A 3 X 2 analysis of variance (speed by pitch) is being employed. To date, 17 veterans have participated in the study. Upon

completion of work with the Mauch Laboratories output, it is expected that a similar design will be used in conjunction with Mr. Harvey Lauer's research at the Central Blind Rehabilitation Center (Hines, Illinois) on the Kurzweil Reading Machine. At the appropriate time, the possibility of similar work with the reading machine currently being developed by Telesensory Systems, Inc., will be explored.

In May, an Am-Bi-Chron (model 402) unit was received. This is used in conjunction with the Library of Congress model C75 cassette player. Plans are also being initiated for purchase of a Variable Speech Control A-6 speech compressor. Recordings from these instruments will be used, with material recorded from a Lexicon Varispeech II and General Electric American Printing House Cassette Player/Recorder with a VSC Module, in a paired comparison-study of speech compressor outputs.

During the current reporting period two veterans received Optacon instruction and were subsequently issued Optacons. One of these veterans (instructed by Mr. Richard R. Bennett) is employed by a large electronics manufacturer and is often required to read computer printouts. Several additional hours of orientation to printouts were included in this training schedule. The veteran felt the ability to read these would allow him to move into other, better-paying, positions with his employer.

#### **Conferences Attended**

In March, Dr. Goodrich, Mr. Bennett, and Mr. Paul attended the "Workshop on Sensory Deficits and Sensory Aids" at Smith-Kettlewell Institute of Visual Sciences. The Conference was jointly sponsored by the Veterans Administration and the Rehabilitation Services Administration. Following the workshop, Mr. Howard Freiburger visited the WBRC. Also during the report period, Mr. Neil Greiner and Mr. Ronald Fenchak attended a "Seminar on Blindness and Diabetes" conducted at the Orientation Center, Albany, California. Mr. Neil Shulman, Chief, Written Communications, and Mrs. Patricia Wagstaff, Blind Rehabilitation Specialist, participated in a Conference on Communications sponsored by the VA at VAH Hines, Illinois. Additionally, Dr. Goodrich was an invited participant in the "Workshop on Rehabilitative Engineering in the State of California," sponsored by the State of California, Department of Rehabilitation, in San Jose, California, on June 28.

#### **Papers and Publications, 1977**

Ault, C.: Diabetes and Blindness. Inservice Training at the Renal

#### Other VA Research Programs

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- Quillman, R. D.: Use of Monocular Devices. Presented to San Mateo County Schools, San Mateo, California, January 1977.
- Wiley, J. K., G. L. Goodrich, R. R. Bennett, and N. C. Darling: Clinical Application Study of Reading and Mobility Aids for the Blind. *Bull. Prosthetics Res.*, BPR 10-27, Spring 1977.

#### The Development of Improved Techniques for the Analysis of Hearing Aid Performance

BioCommunications Laboratory  
University of Maryland  
College Park, Maryland 20742

VA Hospital  
Washington, D.C. 20422

G. Donald Causey, Ph. D., Jerry L. Punch, Ph. D., Howard C. Schweitzer, Ph. D., Earleen Elkins, Ph. D. and Lucille Beck

#### Hearing-Aid-Quality Judgments

Initial studies have been completed on hearing-aid-quality judgments. Test and retest data were collected on listeners having normal hearing and on a group of listeners having audiometrically homogeneous sensorineural hearing loss of mild to moderate degree. Stimuli, including speech of a male talker, speech of a female talker, and music, were processed by five hearing aids exhibiting a variety of electroacoustic characteristics. A paired-comparison tech-



nique was utilized since it represents a method adaptable to a clinical procedure. The pertinent findings of this work are that: (i) the test-retest reliability for the male and female voice (speech) conditions was found to be excellent among both normal and sensorineural listeners, while the reliability for the music stimulus failed to reach statistical significance within either group, (ii) hearing aid preferences assigned for one stimulus, in spite of the basically poor reliability for the music condition, were statistically associated with preferences assigned for either of the other two stimuli, (iii) normals and sensorineurals assigned similar rankings to the hearing-aid-processed conditions, and (iv) there was a lack of hearing-aid-listener interaction within either group of listeners when individual subject data were considered.

Overall, the results suggest that quality judgments of hearing-aid-processed speech provide a differentiating and reliable index of performance with hearing aids differing only subtly in electroacoustic characteristics.

#### **Transient Distortion**

In addition to the phased-array technique already developed for use in measurement of transient response in hearing aids with dynamic compression circuitry, we are currently attempting to adapt a spark-gap technique for use in transient distortion measurements. The latter technique precludes altogether having to use a loudspeaker as the signal source, allowing the production of an acoustically undistorted rectangular pulse. Heretofore, the inability to produce a suitable signal has been the major obstacle to successful measurement of this particular characteristic of hearing-aid performance.

The spark-gap technique will be employed in measurements of decay times in a variety of hearing aids for the purpose of deriving step response values. These values will be incorporated in the design of a proposed digital microprocessor circuit. This circuit, in turn, will be used to manipulate step-response in studies of the isolated effects of transient distortion on speech intelligibility and speech quality, in both normal and hearing-impaired listeners.

#### **Determination of Formant Transition Thresholds as a Function of Compression Hearing Aid Processing**

Data on the processing of sound formant transitions (critical elements of the speech signal for understanding) by commercially available compression hearing aids are now being collected. Compression aids comprise an increasing proportion of all hearing aids

manufactured. There are several operating features of these aids which have undetermined significance for the user. The effects of the compression ratio and the stage of compression activation (input or output stage) are being examined in this project.

Using equipment obtained on loan from Gallaudet College for the Deaf, a technique has been developed for determining the influence of the compression features of interest on the threshold of detection for second formant transitions. This work has important clinical ramifications since many arbitrary design decisions have been incorporated into the commercially available compression aids.

#### **Investigation of Transient Response for Compression Aids**

In conjunction with the National Bureau of Standards, the attack and release times of 81 compression aids were measured. Until 1976 there was no standardized method for these important determinations. The current operating characteristics of 27 different models of compression aids were measured and reported. This information is of notable interest to the developers of the standard, to audiological clinicians, and to hearing-aid engineers. The majority of the total of 81 aids tested had attack times equal to or less than 10 ms. Slightly more than one-half had release times (according to the new measurement protocol) of 50 ms or less. The range of both characteristics was rather large.

#### **Effects of Distortion on Intelligibility-in-Noise Study**

A followup study to an experiment on tonal perception in hearing aids with high and low distortion involved evaluating the influence of the distortion on speech intelligibility in noise. Using a Modified Rhyme Test, we collected data on 30 subjects. The results indicated that nominally high harmonic and intermodulation distortion could not be shown to relate directly to a reduction in listener performance in noise. This work underscores the importance of the test arrangements in predicting the effects of non-linear distortion in hearing aids.

#### **Collection of Three-Band Listening Level Data**

Considerable interest has recently emerged in multiple-band compression systems for the acoustically handicapped. The rationale is that different compression ratios are required in different frequency regions and these should be "custom" designed for the individual. In the absence of psychoacoustic data which support the widespread need for such complicated signal processors for

hearing-aid users, collection of suprathreshold data (most comfortably loud and uncomfortably loud levels) in three frequency regions on a large population of *sensorineurally-impaired* patients has begun. The frequency regions are similar to those which some investigators have for multi-band compression circuits.

Data from this study will help predict the percentage of patients who may be candidates for multi-band compression applications. Without such basic information clinicians may be persuaded that all patients are potentially to benefit from such sophisticated systems when, in fact, only a small portion may qualify.

#### **Analysis of the Effectiveness of Dichotic Signal Processing**

Initial efforts have been completed in the area of dichotic amplification for the acoustically impaired. This mode of amplification (dissimilar frequency bands to the two ears) has intriguing theoretical advantages which have been inadequately explored. Progress has now advanced past the design stage and efforts are directed toward the complicated instrumentation phase. Using intelligibility materials in multi-talker competition, a comparison of performance in the dichotic mode versus conventional monaural and binaural modes will be conducted. Behavioral data are expected by late summer, 1977. This work may have a significant bearing on the nature of future amplification devices for hearing-disabled veterans.

#### **Binaural High-Frequency-Emphasis Amplification**

Although patients with hearing loss of ski-slope type have good hearing in the low frequencies, a recent study has demonstrated that they can benefit significantly from use of a hi-pass hearing aid in each ear. With one aid only, one might expect the good hearing for low frequencies on the unaided side to serve satisfactorily in providing a binaural effect. However, this was not the case. There was a 12 percent mean improvement when two aids were employed. In another study using patients with similar high frequency hearing loss, the contribution of various competing messages with three signal/noise ratios to the evaluation of hearing aids is being measured. The results can influence the development of a standardized hearing-aid evaluation technique badly needed within the VA.

#### **Clinical Application Study of Reading and Mobility Aids for the Blind Eastern Blind Rehabilitation Center**



**VA Hospital**

**West Spring Street, West Haven, Connecticut 06516**

**Donald E. Garner, William R. De l'Aune, Ph. D., and**

**Patricia D. Gadbaw**

During this reporting period a seminar on Low Vision and Mobility was held at the Eastern Blind Rehabilitation Center. Mobility instructors from the Connecticut State Agency for the Blind, the New York Association for the Blind, and from the Veterans Administration participated. At this seminar Ms. Gadbaw presented information about the Center's research on the use of prisms by blinded veterans with restricted visual fields. Dr. De l'Aune spoke to the group on research in general and its particular applications to the problems of the peripatologist.

A paper entitled "Optacon Skill Acquisition by Blinded Veterans" by Ms. Gadbaw, Ms. Mary T. Dolan, and Dr. De l'Aune was published in the *Journal of Visual Impairment and Blindness*, 71(1):23-28, Jan. 1977. This paper summarized much of the data on this device that has been accumulated in the past 4 years, and compares the EBRC findings with data obtained from other published Optacon projects.

Two papers by EBRC authors emphasized the importance of psychological attributes of the user of sensory aids in the efficiency of this particular man-machine interaction. The papers were: "Speech Compression: Personality Correlates of Successful Use" (*J. Visual Impairment and Blindness*, 71(2):66-70, Feb. 1977) and "Correlates of Successful Speech Compression Use by Blinded Veterans" (*in Proc. Third Louisville Conf. on Rate Controlled Speech*, Emerson Foulk, ed., New York, American Federation for the Blind, Inc., pp. 219-229, 1975). The authors in each case were Dr. De l'Aune, Mr. Chester Lewis, Dr. Walter Needham, and Mr. James Nelson. The papers also stressed the great potential of speech-compression systems as a communicative aid for the visually impaired.

A paper, "Personality Determiners of Successful Prosthetics and Sensory Aid Use", was presented by Dr. De l'Aune at the Fifth New England Bioengineering Conference in Durham, New Hampshire. It was subsequently published in the *Proceedings* (Michael Cannon, ed., New York, Pergamon Press, pp. 111-115, 1977). In this paper, based on the computerized accumulation of demographic, psychological, and medical data on EBRC clients, the personality characteristics of blinded veterans seen at the EBRC and the effects of these characteristics on their use of currently available aids were covered.

Dr. De l'Aune spoke about "Special Aids for the Blind" at the East Coast Visual Impairment Service Team (VIST) Training Seminar held in New Haven, Conn. He also served as a participant in a joint RSA/VA conference on sensory aids, which was held in San Francisco, Ca.

The research staff of the EBRC cooperated in the analysis of data obtained from a national survey of agencies participating in an RSA evaluation of the Snipas Glucose Analyzer. Through coding and computer processing, a statistical breakdown was provided to Mr. Howard Freiburger for use in this evaluation. Further analysis of this information at RSA is anticipated.

Research into the effects of hearing-aid use on the mobility performance of the visually impaired veteran is being continued by the research and mobility staffs of the EBRC. Because of the sharp increase in the number of blinded, hearing-impaired veterans participating in the blind center programs, the sample size is slowly being expanded to the point at which statistical analysis of the data can begin.

Ms. Gadbaw and Dr. De l'Aune were both involved with the training of a totally deaf and blind veteran to use and program an HP-25C calculator with the aid of his Optacon. The training was judged as successful and the client intends to use his new skills in pursuit of his engineering interests.

Preliminary meetings have taken place to evaluate the feasibility of a VA-sponsored series of meetings to design an inexpensive set of manuals and devices intended to provide a sensorially "normal" person with a simulation of visual and auditory impairments of varying types and degrees. While it was acknowledged that the truly realistic simulation of a great number of pathologies could not be accomplished, it was believed that with careful writing of the accompanying text, careful analysis of the tasks to be undertaken, and thorough understanding of the limitations of these simulators, such devices could be of great value.

**Compression Amplification and Speech Intelligibility in Noise**  
**Audiology and Speech Pathology Service**  
**VA Hospital**  
**University Drive C**  
**Pittsburgh, Pennsylvania 15240**  
**Jing J. Sung, Ph. D.**

The initial phase of this study is an investigation of the influence of various methods of compression amplification on speech intelli-

gibility, and an evaluation of the effectiveness of compression amplification in reducing tolerance problems when loud sounds are encountered. The three types of compression amplification systems under study are the automatic volume control (AVC), the fixed-ratio (2 to 1), and the variable-ratio compression systems. (Comparisons are also to be made between compression and conventional linear amplification systems in terms of speech discrimination ability in noise, and in measures of tolerance.)

A wearable master hearing aid with switch-selectable controls was designed and built by a hearing aid manufacturer for this study. The hearing aid is housed in a pocket-size package which is connected, via a miniature cable, to a post-auricular module. This module contains a forward-facing omnidirectional microphone and a receiver. The pocket package houses the battery, volume control, electronic circuitry and selector switches. An 18-inch cable connects the two units.

Measurements of the electroacoustic characteristics of the master hearing aid were obtained using the ANSI 1976 standard. Included in these measurements were the full-on gain, the HF-average of Saturation Sound Pressure Level 90 (SSPL 90), the frequency response, and the transfer function of the four different types of amplification systems. Furthermore, the amplitude non-linearities of the four systems were measured using three different distortion measurements: harmonic, difference-frequency, and intermodulation distortion.

Twenty-four subjects with bilateral sensorineural hearing loss will be used in this study. The Northwestern University Auditory Test No. 6 will be used as test material to assess subject's discrimination ability.

**Development of a Hearing-Aid System with Independently  
Adjustable Subranges of Its Spectrum Using Microprocessor  
Hardware**

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**Digital Systems Applications to Hearing Aid Research**

Work performed at the Electrical Engineering Department of Colorado State University under the VA project on Digital Systems Applications to Hearing Aid Research, over the period January 1, 1977 to June 30, 1977 was as follows:

1. Design of a harmonic distortion tester — to facilitate controlled tests of harmonic distortion with controllable amplitudes and frequencies.
2. Design of a transient distortion tester — to facilitate controlled tests of transient distortions with controllable frequencies and overshoot rate.
3. Preparation of hardware and analog/digital interface system for final testing of a microprocessor staircase-approximation digital filter for use in hearing aids, where up to 6 discrete, controllable, frequency ranges are separately controllable, and completion of test procedure for above.

## NOTES AND NEWS

### **VERNON L. NICKEL, M.D., APPOINTED DIRECTOR OF VA REHABILITATIVE ENGINEERING SERVICE**

Dr. Vernon L. Nickel has been appointed director of the Veterans Administration Rehabilitative Engineering Research and Development Service. He assumed the new position in Washington, D.C., on October 1, 1977.

Dr. Nickel, a diplomate of the American Board of Orthopaedic Surgery, is well known for his work with the handicapped and in the application of engineering science and technology to their problems. He comes to the VA from Rancho Los Amigos Hospital, Downey, California, where he was Chief of Surgical Services from 1953, Medical Director from 1964 to 1970, and co-director of the hospital's Rehabilitation Engineering Center since 1970. His program at Rancho Los Amigos was listed in 1973 among the Top Ten Engineering Achievements in the United States.

Dr. Nickel will have administrative responsibility for the entire program of the Veterans Administration's Rehabilitative Engineering Research and Development Service, which was organized in 1975. The service, one of the three components of the VA's Research and Development Office, grew out of the VA Prosthetic and Sensory Aids Service, formed in 1948. Research is sponsored at VA hospitals, at the VA Prosthetics Center in New York City, and through contracts with private organizations.

### **DR. ROSALYN S. YALOW AND DR. ANDREW V. SCHALLY OF THE VA ARE NOBEL PRIZE WINNERS IN MEDICINE**

Dr. Rosalyn S. Yalow of VAH, Bronx, New York, and Dr. Andrew V. Schally of VAH, New Orleans, Louisiana, were 1977 Nobel Prize winners in medicine. Both are VA career doctors and senior medical investigators. Dr. Yalow, who was awarded one-half of the \$145,000 prize, is the second woman ever to win a Nobel Prize in medicine.

Dr. Yalow's award honored her development of radioimmunoassays of peptide hormones. The Nobel citation said she and her co-workers had directed diabetes research "into new tracks" and given such research "a new dimension . . . this modern endocrinology con-

tinues to develop and gives us continuously new outlooks on the causes and nature of diseases within the whole spectrum of medicine.”

The remaining half of the Nobel Prize in medicine was shared by Dr. Schally and Dr. Roger Guillemin, of the Salk Institute in San Diego, California, for discoveries concerning the peptide hormone production of the brain.

**MAX CLELAND AND HOWARD A. RUSK  
HONORED IN 1977 JEFFERSON AWARDS**

The 1977 Jefferson Awards presented by the American Institute for Public Service were given to Max Cleland, Administrator of the Veterans Administration, for “the greatest public service by an individual under 35,” and to Dr. Howard A. Rusk, Director, Institute of Rehabilitation Medicine, New York, for “greatest public service benefiting the disadvantaged.”

**NEW REHABILITATIVE ENGINEERING RESEARCH AND  
DEVELOPMENT CENTER ESTABLISHED AT VAH, HINES, ILLINOIS**

A new facility, which is expected to employ about 30 engineers and scientists by 1979, has been opened at the Hines VA Hospital, near Chicago. According to the announcement of the new center's opening by VA Administrator Max Cleland, its program will emphasize work on a full range of projects designed to restore mobility to injured veterans, including restoration of “at least some mobility” to patients now considered permanently paralyzed.

Among the new Rehabilitative Engineering Research and Development Center's goals is the achievement of new levels of effectiveness in bringing together the skills of various scientific and professional disciplines, and focusing them together upon the problems of the injured veteran. A related goal will be to make extensive use of new products, and of techniques such as electronic miniaturization, many of which are developments of the Nation's space program.

**PCEH “PHYSICIAN OF THE YEAR” AWARD FOR 1977  
GOES TO ROBERT L. BENNETT, JR., OF ATLANTA**

The Physician of the Year Award, of the President's Committee on Employment of the Handicapped, was awarded to Robert L. Bennett, Jr., M.D., who is Professor of Rehabilitation Medicine at Emory University School of Medicine, Atlanta, Georgia.



The award, presented during the 37th Annual American Medical Association Congress of Occupational Health in St. Louis, Missouri, honors the physician who has made the "most significant contribution to the employment of handicapped persons during the previous year."

Dr. Bennett is responsible for the design and refinement of numerous orthotic devices. He is particularly noted for his management of the post-polio patient. He has also been a major force in development of the Georgia Rehabilitation Center by the State of Georgia, on lands given to the state by the Georgia Warm Springs Foundation in 1962.

#### HELEN KELLER NATIONAL CENTER DEDICATED

The new Helen Keller National Center, for deaf-blind youths and adults, at Sands Point on the North Shore of Long Island, New York, was dedicated in the Fall of 1977. The Center is operated by the Industrial Home for the Blind, Brooklyn, N.Y., under what is described as "a definitive agreement" with the Federal Government. Harry Spar is Director of the Center.

Design of the Center features such details as bed vibrators to awaken residents, flashing light alarms for those with residual vision; an emergency "chute" exit; electrical defrosting of paths between residence and training buildings; and electric fans which move air to tell an occupant that a doorbell button has been pressed.

The Helen Keller National Center reported that it had eight regional offices and representatives, to screen potential trainees and to follow up on their job training and placement. Locations were listed at Sands Point, Long Island, N.Y., Philadelphia, Pa., Atlanta, Ga., Chicago, Ill., Dallas, Texas, Denver, Colo., Seattle, Wash., and Glendale, Ca.

#### DECLARATION OF RIGHTS FOR THE DEAF-BLIND ADOPTED BY HELEN KELLER WORLD CONFERENCE

A declaration asserting the rights of all deaf-blind persons was adopted by the Helen Keller World Conference on Services to Deaf-Blind Youth and Adults, held in September 1977 in New York.

The Declaration adopted by the Conference refers first to those rights described in the United Nations Declaration of Human Rights, and the United Nations Declaration on the Rights of Disabled Persons. It also specifies the following: the right to lead a normal life in the community, to receive the best possible medical treatment,

to economic security, to marry and raise a family, to secure work commensurate with capabilities, to the services of an interpreter at no cost, to current news, to recreational activities, to be consulted on all matters of direct concern, and to receive legal advice and protection against abridgement of these rights.

Copies of the Declaration are reported to be available from the sponsor of the Conference, the World Council for the Welfare of the Blind, 57 Avenue Bosquet, 75007 Paris, France.

**"INDEPENDENCE WITH DIGNITY: ACTION '78" IS THEME  
OF 2nd NATIONAL CONFERENCE ON AGING AND BLINDNESS**

The 2nd National Conference on Aging and Blindness will be held in Atlanta, Georgia, March 27-30, 1978. Among conference goals are development of information and recommendations for the White House Conference on Aging in 1981.

Conference co-chairmen are Roy Kumpe, who has retired as executive director of the Arkansas Enterprises for the Blind, and Harry F. Walker, deputy director of the State of Maryland Office on Aging, and also chairman of the Advisory Committee on Aging of the American Foundation for the Blind. Conference coordinator is Dorothy Demby, AFB specialist on aging.

Joint sponsors of the conference are the American Foundation for the Blind, and the Department of Health, Education, and Welfare (DHEW) Administration on Aging, and Office for the Blind and Visually Handicapped.

**GLOWING CANE FOR THE BLIND TRAVELER**

Figure 1 illustrates three views of the LouChek Night Cane. At "B" the tip end is shown with its replaceable nylon tip and, above it, the clear "window" section of the cane. Within the transparent section can be seen a length of the translucent light-carrying and light-emitting rod which runs through the cane from the inner end of the tip to the bottom of the handle.

At "A" a nearly full-length view of the cane is shown.

At "C" an enlarged view shows the part of the handle where the on-off light switch is mounted.

The cane has a No. 22 miniature lamp powered by two Size AA batteries. Its light, carried by the central translucent rod, is emitted at the clear "window" section of the cane and also causes the white polyolefin-covered shaft to glow in the dark.

This cane is considered an optional item in the armamentarium of the blind traveler. The manufacturer, LouChek Products of 870 S. Gramercy Place, Los Angeles, California 90005, feels that the cane gives an extra measure of safety for a blind person because it glows visibly in the dark.

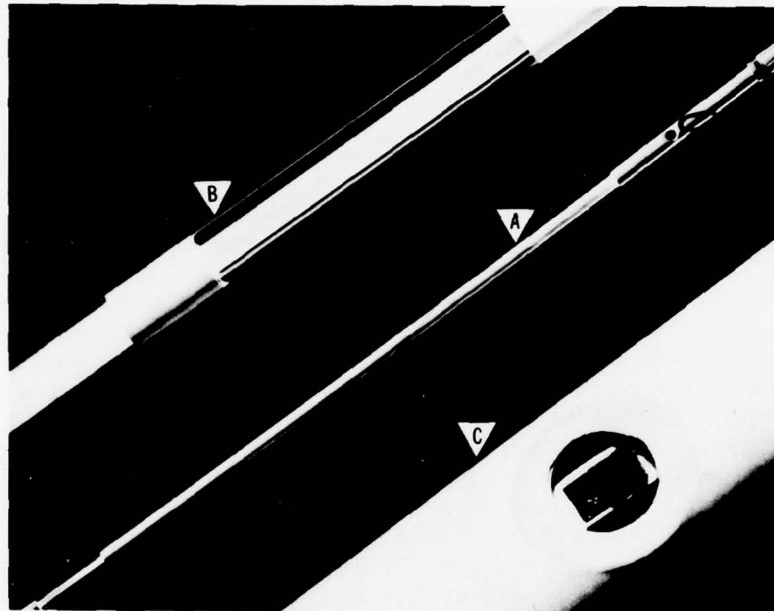


FIGURE 1.—Three views of the LouChek Night Cane.

#### NOW, "HEARING-EAR DOGS" FOR THE DEAF

The Journal of the American Speech and Hearing Association reports an innovative program, by the American Humane Association, in which dogs are being trained to assist deaf and hearing-impaired individuals.

The dogs, chosen for intelligence and disposition, are trained to alert their owners to specific sounds such as the crying of an infant, a knock on the door, clock alarms, and smoke detector signals. They are also trained to respond to hand signals.

The "hearing-dog" program originated with the AHA Minnesota branch but has been moved to AHA headquarters in Denver, Colorado, where it is under the direction of Robert White. He is described as a



professional educator of the deaf who is also an experienced animal trainer. Mr. White was quoted as saying that he expected "hearing dogs" to someday outnumber dogs trained to assist the blind.

AHA is reported to be seeking financial assistance for a major enlargement in the dog training program, with 10 regional centers to be opened. About 50 dogs have been provided at no cost to recipients, but the cost of the 3-to-4 month training program for each animal was said to be "around \$1,400."

**AAAS PROJECT ON THE HANDICAPPED IN SCIENCE EMPLOYS  
CHERYL A. DAVIS AND RECEIVES \$185,000 IN GRANTS**

Activities aimed at an early practical payoff for the handicapped college-age student who wants a scientific education and a career in science are in the works for the AAAS Project on the Handicapped in Science. New funds, from a combination of federal and corporate sources, have enabled the project to add to its staff and undertake some new efforts.

Staff additions include Cheryl A. Davis, as a new program associate. She is a wheelchair user who in 1977 completed a year as a Loeb Fellow in Advanced Environmental Studies at Harvard University. A planner and specialist in design of housing and other environments for handicapped persons, she has published widely on such topics as facilitating employment of the handicapped, the role of housing in rehabilitation, and the 1973 Rehabilitation Act.

Cheryl Davis is assisting in the development of a variety of the new AAAS projects. Among them is an inventory of teachers and school administrators who have successfully taught science to handicapped students. A newsletter, Access to Science, is intended to serve as a vehicle of communication among college and university administrators, science departments, guidance counselors, and handicapped students. Studies that are planned include one of the "coping strategies" of handicapped scientists who have successfully acquired an education and achieved a career in their fields.

To carry the message in a manner more personal than is possible on the printed page, they have sent Robert Menchel, a physicist who is deaf, on a 20-state lecture tour.

Funds for these and other new projects of the AAAS Project on the Handicapped in Science (a part of the AAAS Office of Opportunities in Science) were provided by grants from the following sources: the National Science Foundation, the W. T. Grant Foundation, the Bureau of Education for the Handicapped, the Xerox Corp., and the Exxon Corp.

### **PREVENTION OF DISABILITY, AND INTEGRATION OF THE DISABLED INTO COMMUNITY, HEAD LIST OF PROFESSIONALS' PRIORITIES**

The opinions of rehabilitation professionals, international organization representatives, and service providers in 47 countries showed a "consistently clear" pattern of priorities when they were surveyed by Rehabilitation International as part of the groundwork for the organization's 14th World Congress in June 1980.

Prevention of disability was ranked as the single subject of highest priority. Integration of disabled people within the community, the participation of the disabled in the rehabilitation process, and improved delivery of care and services were seen as the next most important areas of concern.

Disability and the family was ranked as the area of next greatest importance.

Both the theme and the scientific program of the World Congress, to be held in Winnipeg, Canada, have been formed in response to the viewpoint revealed in the survey. Features of the program already announced include parallel day-long workshops on the subjects of Disability and the Family, and Participation of Disabled People in the Rehabilitation Process. Roundtable discussions prior to the Congress will seek a draft text of "A Plan of Action for the 80's", which could serve as a blueprint for world action during the decade.

Also planned is a "special event" to memorialize the Decade of Rehabilitation (1970-1980) and concurrently launch the International Year for Disabled Persons proclaimed for 1981 by the United Nations General Assembly.

The president of Rehabilitation International's 14th World Congress is Patricia Harris (Mrs. C. E. C. Harris) who is president of the host organization for the Winnipeg event, the Canadian Rehabilitation Council for the Disabled.

### **"... AND I SAY TO YOU TONIGHT THAT THE TIME FOR DISCRIMINATION AGAINST THE HANDICAPPED ... IS OVER"**

Very well informed observers called the 5-day White House Conference on Handicapped Individuals the largest-ever assembly of handicapped people, and it must also have been the most-varied very large assembly of its kind in terms of handicaps represented in a large group in a non-institutional situation.

President Carter, in addition to declaring that "... the time for discrimination against the handicapped in the United States is over," conveyed in his address a very strong sense of his personal awareness

of the Conference's importance and the effects of its recommendations on the lives of many millions of people, now and in the future. He also spoke of the fact that Congress has given him the reorganization authority he had sought: one of the very good benefits of the reorganization authority, he said, is to bring together into one agency all of the more than 100 different programs the Federal Government already has for the handicapped.

He commented that "... we are not just concerned about the correction of an existing handicap, or an opportunity for those who are handicapped; we want to prevent the handicap that might occur in the future." In this connection he promised to get immunization or inoculation of children against preventable diseases back to a level approaching the 100 percent level again, instead of the 65 percent he said is current.

Among Conference statements by Federal officials there was the comment by Patricia R. Harris, Secretary of the U.S. Department of Housing and Urban Development, that "5 percent of all new family units and public housing programs will be designed for use by the handicapped." She also noted formation within HUD of a new Office of Independent Living for the Disabled, intended to "sensitize" the agency to housing and environmental needs of physically and mentally disabled persons.

Secretary of Transportation, Brock Adams, had announced, just before the Conference, a new policy under which all public buses purchased with DOT grants must be designed for easy access by handicapped and elderly persons. It was estimated that the ruling would cover more than 90 percent of full-size transit buses in operation in the United States.

#### **MORE CONCERN FOR NEEDS OF PHYSICALLY HANDICAPPED LIKELY IN INTERNATIONAL TECHNICAL STANDARDS**

The International Organization for Standardization (ISO), a non-governmental body which develops technical standards which can then be adopted by member organizations in 82 countries, is reported moving toward more formal arrangements for making allowances for disabled people's needs in the technical standards it develops.

ISO is reported considering creating a technical committee on the physically handicapped, which would deal with the subject where it falls outside the scope of other ISO technical committees, and could coordinate the effort where provisions for the handicapped require the involvement of its existing committees in fields ranging from building construction to the design of signs.



Continuing growth of ISO's interest in the needs of the handicapped was reported following a September 1977 meeting of the Rehabilitation International Commission on Technical Aids, Housing, and Transportation, in France. At that meeting, cooperation with ISO was reported to have been one of the main topics of discussion.

#### **AMPUTEE'S MANUAL . . . MAUCH S-N-S KNEE**

A pocket-size 21-page illustrated "Amputee's Manual . . . Mauch S-N-S Knee," is now available from Medic Publishing Co., P.O. Box 1636, Bellevue, Washington 98009. The authors are Bernice Kegel, R.P.T., and James L. Byers, C.P., of the Prosthetics Research Study, Seattle, Washington.

Intended as a supplement to physical therapy training with prostheses incorporating the Mauch S-N-S hydraulically controlled knee, the manual provides detailed practical instructions and suggestions intended to help the user continue to obtain maximum satisfaction and function from the unique features of the device. There are 56 illustrations and a drawing.

The Amputee's Manual was originally published in 1977 for the Veterans Administration Prosthetics Center, 252 Seventh Ave., New York, N.Y. 10001, in cooperation with the Prosthetics Research Study of Seattle, Washington, under VA contract. (VA facilities should continue to request copies from VAPC at the New York City address.)

#### **ROBERT W. MANN, Sc.D., RECEIVES ASME MEDAL**

Robert W. Mann, Sc.D., distinguished Whitaker Professor of Biomedical Engineering at Massachusetts Institute of Technology, Boston, Mass., was presented with the ASME Medal for his outstanding contributions to bioengineering research and education. The ASME Medal has symbolized eminent engineering achievements for many years.

Dr. Mann was presented with the medal at the 1977 American Society of Mechanical Engineering (ASME) Winter Annual Meeting, Atlanta, Georgia.

Dr. Mann is well known for his contributions in engineering research and development in the field of rehabilitation engineering.

#### **TONNES DENNISON, 1894-1976**

Tonnés "Ted" Dennison, formerly Executive Director of the Committee on Prosthetics Research and Development of the National

Research Council which advised the Veterans Administration and other agencies, died of a heart attack in Tucumcari, New Mexico on November 11, 1976. He and his wife were en route from their retirement home in Santa Barbara, California to visit relatives in Oklahoma. He was buried, with a military funeral, in Oklahoma City.

Mr. Dennison was born in Brooklyn, N.Y., September 11, 1894. The family later lived in Plainfield, N.J. Mr. Dennison studied electrical engineering at Cooper Union and Columbia University, and he worked for the New York Edison Company.

After serving as an officer in World War I, Ted was a recruiting officer for the Army. He had amusing anecdotes of his adventures while travelling with a Field Artillery gun and crew to recruit local young men. In the period immediately after the expensive World War I, government accounting became unexpectedly meticulous. He had some problems in explaining that the brass shell cases of surplus saluting shells, which had been discharged to attract audiences for his recruiting speeches, had disappeared as souvenirs.

In later years he engaged in civilian engineering activities including building of power plants and transmission systems. He was involved in numerous developments bringing electric power for the first time to small communities, ranches, and farms scattered throughout the Middle West and South, particularly during the vigorous rural electrification movement in the Thirties.

During World War II he was a civilian engineer for the Army Corps of Engineers supervising the building of various bases. At one base his work was investigated by the then Senator Truman, fresh from a major and prolonged investigation which had uncovered numerous scandals at a nearby base. After only half a day of review, the Truman Committee congratulated Mr. Dennison for his integrity and prudence. His "quarters," originally rumored to be palatial, were in the back of his office and had only an inexpensive cot and shower stall, used when he voluntarily worked overtime. The only cost over-run was entirely explained by an unexpected tropical storm which washed dirt back into miles of ditches which had just been excavated.

Later in his engineering career he served under General F. S. Strong, Jr., a distinguished military engineer then in command of the Alcan Highway, the inland route to Alaska. (By coincidence, Ted had served under General Strong's father in the 40th Division at Camp Kearney, California, in 1918.) Ted's common sense, honesty, and ability appealed to General Strong, and they worked closely together. In 1946, after both had left the service, General Strong became Executive Director of the National Academy of Sciences—National Research Council's Committee on Artificial Limbs. He asked Ted to rejoin him January 1, 1947, on the Com-

mittee staff, where I was then Staff Engineer.

During a crucial period involving coordination of major projects, and the launching of the suction socket schools and followup program, we had an effective team of engineers at the Committee headquarters. General Strong was literally a strong yet flexible administrator. Ted Dennison was an effective planner, organizer, and expeditor. The late Major (later Colonel) Gordon Kjolsrud, loaned by the Army first to the Committee and later for a year to the Veterans Administration, was an able diplomat. He promoted the cooperation of many persons and diverse groups including the rugged individualists who operated several hundred small artificial limb shops and their trade association.

Service in a variety of posts for variously named groups in the NAS-NRC structure led ultimately to Mr. Dennison's appointment on July 1, 1959, as Executive Director of the CPRD. Ted retired July 31, 1962, returning to his former home in Santa Barbara, where some of us occasionally visited him. Those who were privileged to know this thoughtful and warm human being will miss his wise counsel, twinkling smile, and generous concern for others.

Eugene F. Murphy

#### DONALD A. COVALT, M.D., 1906-1977

Doctor Donald A. Covalt, Associate Director, Institute of Rehabilitation Medicine, New York University Medical Center, passed away October 28, 1977.

Dr. Covalt was one of few who are the right people in the right place at the right time. He began his career as a young general practitioner in Muncie, in his beloved State of Indiana, and had been out of Indiana University (B.S. 1932, M.D. 1934) for less than a decade when World War II erupted. He joined the Air Corps and was assigned to organize that service's first rehabilitation center in a pair of commandeered Florida hotels. He did it so well that his commanding officer, Dr. Howard A. Rusk, brought Dr. Covalt to Washington as his Deputy Director. This occurred toward the end of the war, when the Air Force rehabilitation program was already in progress in more than 200 hospitals, and Dr. Rusk was busy getting 10 new rehabilitation centers completed and staffed.

At the end of the war, Dr. Covalt would have preferred either to return to Indiana, or to join Dr. Rusk at Bellevue Hospital in New York where the future of rehabilitation medicine was being explored. But Dr. Rusk convinced him that he had another chore to do before settling down. That chore was, in Dr. Rusk's own words, "to help



General Paul R. Hawley, General Omar Bradley, and Dr. Paul Magnusson organize a rehabilitation program in the Veterans Administration." He took the assignment. His work in convalescence and rehabilitation earned him the Legion of Merit, awarded in 1945. Two-and-a-half years later, Dr. Covalt left the VA, where a rehabilitation program was growing strongly in VA hospitals across the country. He returned, not to Indiana, but to join Howard Rusk in those "two old dilapidated wards" on New York's lower East Side. There he found a few other men and women who felt very deeply about something that hardly anyone else seemed to know or care about. These people knew that, historically, large scale rehabilitation had been mostly a hastily improvised wartime specialty . . . always backward because its gains tended to be lost in the periods between wars. They decided that, this time, wartime gains would be the foundation for peacetime progress, with growth equally dramatic but also sustained and enriched by scientific studies across the entire range of crippling and disabling conditions.

From Bellevue Hospital in New York to an old loft building on 38th Street and First Avenue, and thence to today's renowned and still-growing Institute of Rehabilitation Medicine of the New York University Medical Center, Dr. Covalt worked with his old Air Corps chief. Until 1957 he was Clinical Director of this institution which set the pace for rehabilitation in the United States and much of the rest of the world. Thereafter he was Associate Director, until his death in October 1977.

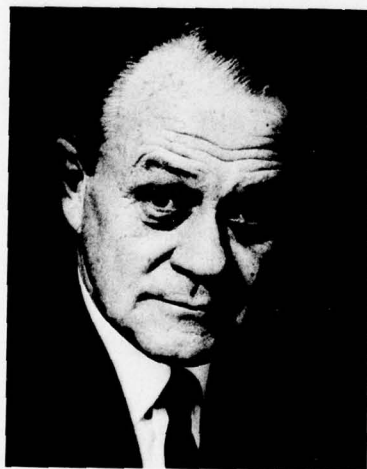


FIGURE 2.—Donald A. Covalt, M.D.,  
1906-1977

Dr. Covalt's career was probably most unusual in the way he was able to take part in large-scale events, which had results that have been truly global, while still remaining a clinician and a practitioner in direct, personal, everyday contact with his patients. Thus, his own influence on large institutional developments helped anchor the institution's policies firmly to the clinical and human realities of life.

His many publications down through the years reflected his viewpoint: in the late '40's, amid papers on the problems of returning veterans, there was a series on the rehabilitation of children. Rehabilitation of the amputee and the hemiplegic patient formed the bulk of his published work, with occasional pieces on the value of dynamic treatment in chronic disease and spinal cord injury. He was interested in the role of the therapist, and the employment of total medical resources, i.e., laying the foundation of the "team approach." And his list of titles repeatedly used such words as "hope," "new hope," and "new vision," testifying to the identification with the patient as a fellow human being.

Dr. Covalt was a Diplomate, American Board of Physical Medicine and Rehabilitation, and a past president of the American Congress of Physical Medicine and Rehabilitation Medicine: at that time he received the Gold Key Award.

He served as a consultant in the planning of rehabilitation facilities to various hospitals and medical centers throughout the United States and Canada, as well as serving as Vice-chairman, Medical Committee, the President's Committee on Employment of the Physically Handicapped.

Dr. Covalt is survived by his mother, wife and daughter, brother, and two sisters.

Tamara T. Sowell

#### CHARLES LE ROY LOWMAN, 1879-1977

Dr. Lowman, a distinguished orthopedic surgeon with numerous contributions to rehabilitation of patients with a variety of difficulties, died after a brief illness in the Orthopaedic Hospital, Los Angeles, California, which he had founded in 1922. He had been very active until shortly before the end of his long, illustrious, and vigorous life.

Dr. Lowman had been born in Park Ridge, Illinois on December 25, 1879 but had moved to Los Angeles in 1900. He graduated from the University of Southern California Medical School in 1907, served as an intern at the California Lutheran Hospital, and studied orthopedic surgery at Massachusetts General Hospital, Carney Hospital, and Children's Hospital, in Boston, Massachusetts, where much of the pioneering work in orthopedic surgery was developing at the time.

Even after he ostensibly retired from his responsibilities as Chief of Staff of the Orthopaedic Hospital in 1945, at the age of 65, he remained extremely active both for that institution and in a variety of other activities. For many years he frequently flew to Calexico, at the border between California and Mexico, to help staff the Valley Orthopedic Clinic, which supplied free medical care for polio victims and other handicapped children from both the United States and Mexico. Unfortunately the polio vaccines were not widely used in Mexico, and epidemics continued long after they disappeared in the United States. Some of the other staff members from the Orthopaedic Hospital, whom he inspired to go to Calexico for weekends to serve as volunteers, have continued to serve there after their formal retirement from the Orthopaedic Hospital.

In addition to meeting him on many occasions, especially at many meetings of the American Academy of Orthopaedic Surgeons, I recall with great pleasure a prolonged visit with him on a train to Los Angeles many years ago, close to the end of World War II. Both Miss Helena T. Mahony and Mrs. Vera Rickman Ford, who had been physical therapists at Warm Springs when I was a patient there, had later served on the Orthopaedic Hospital staff. We reminisced about them as well as discussing orthotics problems as we rode across the dry but everchanging West. I occasionally visited the Hospital.

Dr. Lowman was an extraordinarily active and vigorous person with strong ideas about the desirability of exercises. He continued to exercise even when strapped into an airplane seat during his frequent travels. Among his numerous publications was a note on the desirability of isometric exercises to maintain circulation while flying.

He received numerous honors, including the nation's highest civilian honor, the Presidential Medal of Freedom. Undoubtedly thousands of patients are grateful for his personal care. Much larger numbers of handicapped whom he never treated personally have benefitted from his long concern for total patient care, including education for the children during their stay in the hospital. It was both a privilege and a pleasure for me to know this fascinating and devoted friend and servant of humanity for so many years of what was really his nonretirement.

Eugene F. Murphy



## RECENT PATENTS<sup>a</sup>

**Artificial Hand:** Eino Pihlaja. An artificial hand for the amputee whose hand stump includes the metacarpal joints. Four finger-like members are collectively actuated in opposition to a fixed set of claws. (Patent No. 4,016,607, April 12, 1977; filed July 30, 1976, Appl. No. 710,028; 11 claims.)

**Artificial Limb with Three-Part Cosmetic Covering:** Herbert Thompson, assignor to Chas. A. Blatchford & Sons, Ltd., Basingstoke, England. An artificial leg of the endoskeletal type is equipped with an outer covering of two or more parts. When worn, parts of the cover section can be readily replaced. (Patent No. 3,953,900, May 4, 1976; filed Feb. 25, 1975, Appl. No. 553,009; 11 claims.)

**Artificial Wrist and Arm Prosthesis:** Eduard Horvath, assignor to Otto Bock Orthopädische Industries KG, Duderstadt, Germany. An artificial wrist to serve as a connector between an arm prosthesis and various hands or implements. Rotation is provided by rolling elements; axial motion by a bushingpin combination. (Patent No. 4,010,495, March 8, 1977; filed May 15, 1974, Appl. No. 470,080; 52 claims.)

**Bifocal Lens Which Positions Within the Anterior Chamber:** Charles W. Neefe. A form of lens implant to be employed after cataract surgery. An air space is used at the upper lens edge to position the lens properly with respect to the pupil. It is claimed that reading is possible under conditions of low illumination. (Patent No. 4,010,496, March 8, 1977; filed Oct. 1, 1975, Appl. No. 618,382; 1 claim.)

**Electronic Hearing Apparatus:** Alfred A. A. Tomatis. Cascade amplifiers are arranged to actuate the inner ear through a transducer, thereby producing a number of claimed effects including: a reduction of some types of vertigo, better hearing through delivery of optimum frequency bands to the middle ear, and the elimination of some forms of asthma, coughing, etc. (Patent No. 4,021,611, May 3, 1977; filed April 23, 1976, Appl. No. 679,873; 8 claims.)

**Fluted Hip Nail Implant System for Orthopaedic Surgery:** Albert H. Burstein and Kingsbury G. Heiple, assignors to the Sampson Corp., Pittsburgh, Pa. A fluted one-piece hip nail and bone plate system employing sharp edges for cutting into bone and providing torsional rigidity. It is claimed that the resulting nail provides improved bending strength in the fixation of fractures. (Patent No. 4,009,712, March 1, 1977; filed Aug. 7, 1975, Appl. No. 602,725; 14 claims.)

**Inflatable Sole Shoe:** Dennis J. Gager, assignor to The Raymond Lee Organization, Inc., New York, N.Y., a part interest. A shoe equipped with a hollow sole capable of being filled with any fluid under pressure. When so inflated, it is claimed that the shoe conveys a sense of comfort and springiness to the wearer which reduces fatigue. (Patent No. 4,008,530, Feb. 22, 1977; filed Jan. 5, 1976, Appl. No. 646,614; 1 claim.)

<sup>a</sup>Patents may be ordered by number from the Commissioner of Patents, Washington, D.C. 20231, at 50¢ each.

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**Implantable Neural Electrode:** R. B. Stein, Dean Charles, and Allan Mannard. An implantable electrical unit permits a direct connection between external devices and the nervous system. It is claimed that the method employed provides for the regeneration of severed nerve fibers in passageways. (Patent No. 3,955,560, May 11, 1976; filed June 10, 1974, Appl. No. 477,644; 12 claims.)

## PUBLICATIONS OF INTEREST

### PROSTHETICS

**Application of a Three-State Myoelectric Control System**, William F. Sauter; *Inter-Clinic Info. Bull.*, XVI(1,2):9-12, Jan.-Feb. 1977.

**Artificial Sensory Communications via the Tactile Sense—Space and Frequency Optimal Displays**, Moshe Solomonow and John Lyman; *Ann. Biomed. Engng.*, 5(3):273-286, 1977.

**Biofeedback and the Lower Extremity Amputee—a New Training Aid**, Bernice A. Zimnicki and Geoffrey R. Fernie; *Physiother. Canada*, 28(2):1-3, May 1976.

**The CAPP Two-Way Shoulder Joint**, Yoshio Setoguchi, Carl Sumida, and Julie Shaperman; *Inter-Clinic Info. Bull.*, XVI(1,2):1-8, Jan.-Feb. 1977.

**A Cosmetic Functional Hand Incorporating a Silicone Rubber Cosmetic Glove**, E. W. Davies, W. B. Douglas, and A. D. Small; *J. Int. Soc. Pros. & Ortho.*, 1(2):89-93, Sept. 1977.

**The Design of a Wireless-Controlled Intra-Oral Electrolarynx**, Siegfried G. Knorr and Daniel H. Zwitman; *J. Bioengng.*, 1(3):165-171, 1977.

**Elements of Hip Joint Prosthesis Reliability**, John H. Dumbleton; *J. Med. Engng. & Tech.*, 1(6):341-346, Nov. 1977.

**Functional Analysis of the UC-BL Shank Axial Rotation Device**, L. W. Lamoreux and C. W. Radcliffe; *J. Int. Soc. Pros. & Ortho.*, 1(2):114-118, Aug. 1977.

**A Heat Generating Socket**, John Ficociello, Thomas Trudell, and Albert Hebert; *Ortho. & Pros.*, 31(3):41-43, Sept. 1977.

**Initial Prosthetic Fitting of the Congenital Below-Elbow Amputee—Are We Fitting Them Early Enough?** Anne G. Fisher; *Inter-Clinic Info. Bull.*, XV(11,12), Nov.-Dec. 1976.

**Integrated Behavior of Artificial Skin**, Z. Stojiljković and J. Clot; *IEEE Trans. Biomed. Engng.*, BME-24(4):396-399, July 1977.

**Kinesiologic Measurements of Functional Performance Before and After Geometric Total Knee Replacement—One-Year Follow-up of Twenty Cases**, Michael C. Collopy, M. P. Murray, Gena M. Gardner, Robert A. DiUlio, and Donald R. Gore; *Clin. Orthopaedics and Rel. Res.*, (126):196-202, July-Aug. 1977.

**Need for Permanent Prosthetic Attachment Demands Development of Biologic Mechanism**, A. M. Weinstein, and J. J. Klawitter; *Orthop. Rev.*, 6(8):15-17, Aug. 1977.



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**New Prospects for a Prolonged Functional Life-Span of Artificial Hip Joints by Using the Material Combination Polyethylene/Aluminum Oxide Ceramic/Metal**, M. Semlitsch, M. Lehmann, H. Weber, E. Doerre, and H. G. Willert; *J. Biomed. Mater. Res.* 11:537-552, 1977.

**Parameters of Stimulation and Perception in an Artificial Sensory Feedback System**, Cedric F. Walker, Gregory R. Lockhead, David R. Markle, and James H. McElhaney; *J. Bioengng.* 1(3):251-260, 1977.

**Pneumatic Supracondylar Suspension for Knee-Disarticulation Prostheses**, A. Bar, R. Seliktar, and Z. Susack; *Ortho. & Pros.*, 31(3):3-7, Sept. 1977.

**The State of the Art in Joint Replacement—Part 2: Present Practice and Results**, S. A. V. Swanson; *J. Med. Engng. & Tech.*, 1(6):335-339, Nov. 1977.

**Techniques of Lower Limb Prosthetic Manufacture Using Lightcast II**, K. Ruder, G. R. Fernie, and J. P. Kostuik; *J. Int. Soc. Pros. & Orth.*, 1(2):84-88, Aug. 1977.

**Traumatic Triple Amputation—Psycho-Social Problems in Rehabilitation**, Madeleine Shaw, Marilyn Kaplow, Nelson Mitchell, and Dorothy Stillwell; *Arch. Phys. Med. & Rehab.*, 58(10):460-462, Oct. 1977.

**Upper-Limb Prosthetic Fitting for a Patient with C-5 Quadriplegia**, George M. Chamberlin, Toulia Latto, and George Berryman; *Inter-Clinic Info. Bull.*, XV(11,12), Nov.-Dec. 1976.

## **ORTHOTICS**

**Cast-Bracing for Fractures of the Femur—a Preliminary Report of a Modified Device**, Benjamin E. Lesin, Vert Mooney, and Milton E. Ashby; *J. Bone & Joint Surg.*, 59-A(7):917-923, Oct. 1977.

**The Design and Prescription of Above-Knee Orthoses**, E. G. Anderson, J. T. Henshaw, and C. Eng; *Ortho. & Pros.*, 31(3):31-40, Sept. 1977.

**Experience with an All-Plastic Patellar Tendon-Bearing Orthosis**, James T. Demopoulos and John E. Eschen; *Arch. Phys. Med. & Rehab.*, 58(10):452-456, Oct. 1977.

**Functional Bracing of Fractures of the Shaft of the Humerus**, Augusto Sarmiento, Philip B. Kinman, Eugene G. Galvin, Roger H. Schmitt and James G. Phillips; *J. Bone & Joint Surg.*, 59-A(5):596-601, July 1977.

**Modern Concepts in Hand Orthotics**, D. McDougall; *J. Int. Soc. Pros. & Ortho.*, 1(2):107-110, Aug. 1977.

**An Orthosis for a Patient with a Failed Total Hip-Prosthesis**, Tim Jacobson and Alanson Mason; *Ortho. & Pros.*, 31(3):27-30, Sept. 1977.

**Orthotic Management of the Unstable Knee**, Arminius Cassvan, Kenneth E. Wunder, and Douglas M. Fultonberg; *Arch. Phys. Med. Rehabil.* 58(11):487-491, Nov. 1977.

**A Podiatric View of Modern Footwear**, Richard O. Schuster; *ASTM Standardization News*, 5(9):18-19, 42, Sept. 1977.

## **Publications of Interest**

**Some Biomechanical Considerations in the Design of Ankle-Foot Orthoses**, David N. Condie and C. B. Meadows; *Ortho. & Pros.*, 31(3):45-52, Sept. 1977.

**VAPC Prescription Procedures for Knee Orthoses and Knee-Ankle-Foot Orthoses**, Gustav Rubin, Malcom Dixon, and Michael Danisi; *Ortho. & Pros.*, 31(3):9-25, Sept. 1977.

## **SENSORY**

**Cerebral Lateralization of Haptic Perception—Interaction of Responses to Braille and Music Reveals a Functional Basis**, Myra Okazaki Smith, Jennifer Chu, and William E. Edmonston; *Science*, (197)4304:689-690, Aug. 12, 1977.

**Communication Through Hearing Aids**, G. Donald Causey; *Bull. N.Y. Acad. Med.*, 53(7), Sept. 1977.

**Current Status of Research on Providing Sight to the Blind by Electrical Stimulation of the Brain**, William H. Dobelle; *J. Vis. Impair. and Blindness*, 71(7):290-297, Sept. 1977.

**A Computer-Controlled Method for Determining the Fields of Visual System Neurons**, Jack Lubowsky; *IEEE Trans. Biomed. Engng.*, BME-24(5):461-466, Sept. 1977.

**Electrophysiological Techniques in Vision**, Lorrin A. Riggs, John C. Armington, Jo Ann S. Kinney, David Regan, D. H. Fender, and T. P. Santoro; *J. Opt. Soc. Am.*, 67(11):1451-1489, Nov. 1977.

**The Handicapped Driver—An Insurer's Point of View**, Michael Mittelman and Walter H. Greenfield; *Arch. Phys. Med. Rehabil.* 58:365-367, Aug. 1977.

**Rehabilitation: Educating the Consumer**, Ruth Perlman Klebaner; *J. Vis. Impair. & Blindness*, 71(7):315-317, Sept. 1977.

**Sensory Devices for the Blind**, C. W. Garland; *J. Med. Engng. & Tech.*, 1(6):319-323, Nov. 1977.

**Timbre Analysis of the Sonicguide**, James Welch; *J. Vis. Impair. and Blindness*, 71(7):309-314, Sept. 1977.

## **GENERAL**

**An Approach to Corrosion Control during Electrical Stimulation**, J. McHardy, D. Geller, and S. B. Brummer; *Ann. Biomed. Engng.*, 5(2):144-149, June 1977.

**An Assessment of Derivative Determining Techniques Used for Motion Analysis (Technical Note)**, J. C. Pezzack, R. W. Norman, and D. A. Winter; *J. Biomech.*, 10(5/6):377-382, 1977.

**On Attempting Selective Blockade of Dorsal Root C Fibers in the Treatment of Chronic Pain Problems**, J. Stovall King, Don L. Jewett, Burton Rutkin, and Charles B. Wilson; *Exp. Neurol.*, 56:241-251, 1977.

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**An Automated Accelerometry System for Gait Analysis**, G. L. Smidt, R. H. Deusinger, J. Arora, and J. P. Albright; *J. Biomech.*, 10(5/6):367-375, 1977.

**Biofeedback 1977: State of the Art and Applications**, F. Ned Dikman and Allan Wetzel; *Med. Electron & Data*, 45:47-51, May-June 1977.

**Bipolar Electrode Assemblage for Multiple Experimental Electromyography**, P. Costa, K. M. C. da Silva, and J. P. Modesto; *IEEE Trans. Biomed. Engng.*, BME-24(5):491-493, Sept. 1977.

**Choosing a Van Lift**, Dean D. Duncan and Make McDermott; *Paraplegia News*, 30(350):11, Nov. 1977.

**The Disabled Need Not Be Handicapped**, 8-pp 2-color brochure describes elements of barrier-free design in washrooms and shower rooms in new construction or remodeling: newly-designed products are pictured and described. Free. Bradley Corp., P.O. Box 309, Menomonee Falls, Wisc. 53051.

**Effect of Load, Speed, and Activity History on the EMG Signals from the Intact Human Muscle**, N. Miller and A. Seireg; *J. Bioengng.*, 1(2):147-155, Jan. 1977.

**Emory Detachable Motor Drive for the Standard Wheelchair**, Ray G. Burdett, Bernard A. Cohen, Carmella Gonnella, Gary W. Kelly, and Alfred F. Morris; *Arch. Phys. Med. Rehabil.*, 58:328-331, July 1977.

**Evaluation of Wound-Covering Materials**, A. D. Schwope, D. L. Wise, K. W. Sell, D. P. Dressler, and W. A. Skornick; *J. Biomed. Mater. Res.*, 11:489-502, 1977.

**An Examination of the Elbow Articulation with Particular Reference to Variation of the Carrying Angle**, A. A. Amis, D. Dowson, A. Unsworth, J. H. Miller, V. Wright; *Engng. in Med.*, 6(3):76-80, Jul. 1977.

**Handbook for Electric-Power Wheelchairs**, ICTA Information Center, Fack S-161 25 Bromma 1, Sweden, 1977. Price 10 Swedish kroner (Skr 10.).

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**A Lifting Wheelchair for Paraplegic Patients**, J. T. Henshaw and K. G. Agarwal; *J. Med. Engng. & Tech.*, 1(6):346-349, Nov. 1977.

**Lower-Limb Amputation for Occlusive Vascular Disease**, Geun-Eun Kim, Anthony Imparato, Dong-Sun Chu, and Sanders W. Davis; *Amer. Surg.*, 42(8):598-601, Aug. 1976.

**Metabolic Energy Cost of Unrestrained Walking**, Raymond L. Blessey, Helen J. Hislop, Robert L. Waters, and Daniel Antonelli; *Phys. Ther.*, 56(9):1019-1024, Sept. 1976.

**A Nonstationary Model for the Electromyogram**, Edward Schweddyk, R. Balasubramanian, and R. N. Scott; *IEEE Trans. Biomed. Engng.*, BME-24(5):417-424, Sept. 1977.

**A Percutaneous Implant Using a Porous Metal Surface Coating for Adhesion to Bone and Velour Covering for Soft Tissue Attachment: Results of Trials in Pigs**, G. R. Fernie, J. P. Kostuik, and R. J. Lobb; *J. Biomed. Mater. Res.*, 11:883-891, Nov. 1977.



#### **Publications of Interest**

**The Popliteus Muscle**, Roger A. Mann and John L. Hagy; *J. Bone & Joint Surg.*, 59-A(7): 924-927, Oct. 1977.

**Relationship Between Residual Hindlimb-Assisted Locomotion and Surviving Axons after Incomplete Spinal Cord Injuries**, E. Eidelberg, D. Strachley, R. Erspamer, and C. J. Watkins; *Exp. Neurol.*, 56:312-322, 1977.

**Return of Myosin Heads to Thick Filaments After Muscle Contraction**, N. Yagi, M. H. Ito, H. Nakajima, T. Izumi, and I. Matsubara; *Science*, 197(4304):685-687, Aug. 12, 1977.

**Simple Equipment Used in Clinical Practice for Evaluation of Locomotion**, Antonio Pedotti; *IEEE Trans. Biomed. Engng.* BME-24(5):456-461, Sept. 1977.

**Stabilization of Spine Fracture in Paraplegic Patients Using a Plaster Cradle**, Lars A. Normell and Ingrid K. Odén; *Scand. J. Rehab. Med.*, 8:11-17, 1976.

**Surface Anatomy—An Instruction Manual**, John V. Basmajian, Illust. by Shirley Jackson; Baltimore, Maryland, Williams & Wilkins Co., paper, 68 pages, 1977.

**The Swing Phase of Locomotion, Part I**, F. J. Maillardet; *Engng. in Med.*, 6(3):67-75, Jul. 1977.

**Tools for Aiding Physically Disabled Individuals Increase Independence in Dressing**, Jacquelyn Orlando Yep; *J. Rehabil.*, 43(9):39-41, Nov.-Dec. 1977.

**The Total Care of Spinal Cord Injuries**, Donald S. Pierce and Vernon L. Nickel (Eds.); Boston, Massachusetts, Little, Brown & Co., Medical Div., 340 pages, 1977.

## **CALENDAR OF EVENTS**

**Orthotics and Rehabilitation Engineering for the Spinal Cord Injured Patient**, N.Y.C., sponsored by AAOP and the Department of Rehabilitation Medicine, New York University Medical Center, May 12-13, 1978. (For information: Hans Richard Lehneis, Ph.D., Director, Orthotics and Prosthetics, Institute of Rehabilitation Medicine, 400 East 34th Street, New York, New York, 10016, 212-OR 9-3200, Ext. 2169.)

**Acoustical Society of America, Annual Meeting**, Kingston, Rhode Island, June 13-16, 1978.

**The Alexander Graham Bell Association for the Deaf, Biennial Convention**, St. Louis, Missouri, June 23-27, 1978. (For information: Convention Dept., A. G. Bell Assoc., 3417 Volta Place, N.W., Washington, D.C. 20007.)

**Rehamex '78: International Fair for the Rehabilitation and Integration of the Disabled**, Basel, Switzerland, July 4-9, 1978. (For information, Secretariat Rehamex '78, Schweitzer Mustermesse, CH-4021 Basel, Switzerland.)

**General Assembly of the International Agency for the Prevention of Blindness**, Oxford, England, July 6-8, 1978. (For information: IAPB, c/o Commonwealth House, Haywards Heath, Sussex RH16 3AZ, England.)

**IRMA III: Congress of the International Rehabilitation Medicine Association**, Basel, Switzerland, July 2-8, 1978. (For information: IRMA III Congress Secretariat, CH-4021 Basel, Switzerland.)

**American Orthopaedic Association, Annual Meeting**, The Homestead, Hot Springs, Virginia, June 26-29, 1978.

**American Corrective Therapy Association, Annual Meeting**, Dunfey's Royal Coach Inn, Houston, Texas, July 10-14, 1978.

**Paralyzed Veterans of America, National Paraplegia Conference**, Hilton Air Plaza Inn, Kansas City, Missouri, July 16-21, 1978.

**Blinded Veterans Association, 33rd Annual Convention**, International Hotel, New Orleans, Louisiana, August 8-12, 1978.

**6th International Symposium on External Control of Human Extremities**, Dubrovnik, Yugoslavia, Aug. 28-Sept. 1, 1978. (For information: Yugoslav Committee for Electronics and Automation, P. O. Box 356, 11001 Beograd, Yugoslavia.)

**3rd International Congress on Biorheology**, La Jolla, (San Diego) Calif., Aug. 28-Sept. 1, 1978. (For information: Dr. John Pinto, Secretary General, The Biorheology Congress, Mail Code M-005, University of California, La Jolla, (San Diego), Calif. 92093.

**European Conference on Disability in the Family, and Naidex '78 Exhibition of Aids for the Disabled**, Brighton Convention Center, Brighton, England, September 18-21, 1978.

## Calendar of Events

(For information: Naidex Conventions Ltd., Temple House, 36 High Street, Sevenoaks, Kent TN13 1JG, England.)

**15th Biennial Mechanisms Conference** will be held as part of the **1978 Design Engineering Technical Conference, ASME**, Leamington Hotel, Minneapolis, Minnesota, Sept. 24-27, 1978.

**Western Orthopaedic Association**, Seattle, Washington, Oct. 1-5, 1978.

**31st Annual Conference on Engineering in Medicine and Biology, (ACEMB)**, Marriott Hotel, Atlanta, Georgia, October 21-25, 1978. (For information: Patricia I. Horner, Suite 404, 4405 East-West Highway, Bethesda, Maryland 20014; tel 301-657-4142.) NOTE: BPR 10-27 gave incorrect information on the date and source of further information about this Alliance for Engineering in Medicine and Biology event.

**2nd Meeting, American Society of Biomechanics**, Ann Arbor, Michigan, Oct. 26-27, 1978.

**American Academy of Physical Medicine and Rehabilitation and American Congress of Rehabilitation Medicine Convention**, New Orleans, La., Oct. 29-Nov. 3, 1978.

**Optical Society of America (OSA), Annual Meeting**, Jack Tar Hotel, San Francisco, California, Oct. 30-Nov. 3, 1978. (For information: J. W. Quinn, Optical Society of America, Suite 620, 2000 L St., N.W., Washington, D.C. 20036.)

**American Orthotic and Prosthetic Association (AOPA), National Assembly**, Town & Country Hotel, San Diego, Calif., Oct. 31-Nov. 4, 1978.

**American Speech and Hearing Association (ASHA)** San Francisco, California, November 18-21, 1978.

**American Society of Mechanical Engineers (ASME), Winter Annual Meeting**, San Francisco, California, December 10-15, 1978.

**5th Asian Conference on Work for the Blind**, Hong Kong, Dec. 1978. (For information: World Council for the Welfare of the Blind, 58 Avenue Bosquet, Paris 75007, France.)

**International Association for Prevention of Blindness Conference**, Kyoto, Japan, 1978. (For information: Dr. W. J. Holmes, 1013 Bishop St., Honolulu, Hawaii 96813.)

**Rehabilitation International Medical Commission, 4th International Seminar**, Southampton, United Kingdom, 1978. (For information: Prof. Dr. Karlheinz Renker, Gesellschaft fur Rehabilitation in der DDR, Harz 42-44 Halle (Saale), German Democratic Republic.)

**American Academy of Orthopaedic Surgeons, Annual Meeting**, Brooks Hall Convention Center, San Francisco, California, Feb. 22-27, 1979.

**American Occupational Therapy Association, Annual Conference**, Plaza Hotel, Detroit, Michigan, April 22-27, 1979.

**11th International Biomaterials Symposium in Conjunction with the 5th Annual Meeting of the Society of Biomaterials**, Clemson University, Clemson, South Carolina, April 28-May 1, 1979.



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**6th Pan-Pacific Conference on Rehabilitation**, Seoul, Republic of Korea, May/June, 1979. (For information: Pyung K. Moon, M.D., vice-president, Korean Society for Rehabilitation of the Disabled, 15-San, Sinchong-dong, Sudaemoon-ku, Seoul, Korea.)

**American Physical Therapy Association, Annual Conference**, Atlanta, Georgia, June 25-29, 1979.

**5th World Conference on the Theory of Machines and Mechanisms**, Montreal, Canada, July 8-13, 1979. (Canadian Council of the International Federation of Theory of Machines and Mechanisms, in cooperation with the USCTOMM.)

**8th Congress of the World Federation of the Deaf**, Sofia, Bulgaria, Sept. 2-11, 1979. (For information: Secretariat General, Union of the Deaf of Bulgaria, 3 Bd U1 Zaimov, Sofia, Bulgaria.)

**6th World Assembly of the World Council for the Welfare of the Blind**, Kaduna, Nigeria, Oct. 3-12, 1979. (For information: WCWB, 58 Avenue Bosquet, Paris 75007, France.)

**Optical Society of America (OSA), Annual Meeting**, Holiday Inn/Americana Flagship Hotel, Rochester, New York, Oct. 7-12, 1979.

**American Orthotic and Prosthetic Association (AOPA) National Assembly**, Washington, D. C., Oct. 23-27, 1979.

**American Academy of Physical Medicine and Rehabilitation and American Congress of Rehabilitation Medicine Convention**, Honolulu, Hawaii, Nov. 11-16, 1979.

**American Speech and Hearing Association, Annual Meeting**, Atlanta, Georgia, Nov. 15-18, 1979.

**American Society of Mechanical Engineers (ASME), Winter Meeting**, New York, N.Y., Nov. 25-30, 1979.

**Second International Symposium for Facial Prostheses**, England, 1979. (Note: this is the tentative re-scheduling of a meeting announced for May 4-6, 1978, and cancelled.)

**American Academy of Orthopaedic Surgeons**, Atlanta, Georgia, Feb. 7-12, 1980.

**14th World Congress of Rehabilitation International**, Winnipeg, Canada, June 22-27, 1980. (For information: Canadian Council for the Disabled, Suite 2110, One, Yonge Street, Toronto, Ontario M5E 1E8, Canada.)

**American Speech and Hearing Association**, New Orleans, Louisiana, Nov. 5-9, 1980.

**International Society for Prosthetics and Orthotics (ISPO)**, the Netherlands, 1980.

**(Tentative) American Orthotic and Prosthetic Association (AOPA), National Assembly**, Toronto, Ontario, Canada, 1980.

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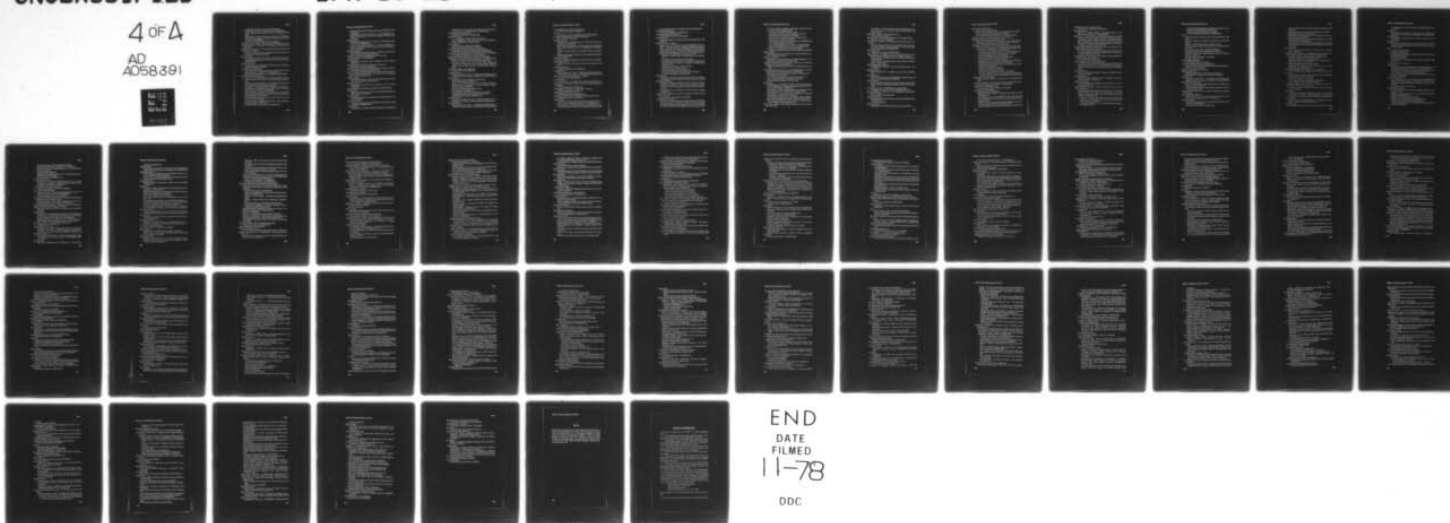
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**ERRATA**

Readers are advised of an error in the Calendar of Events section of the preceding issue (BPR 10-27, Spring 1977). On page 217 of that issue, the announcement of the 31st Annual Conference on Engineering in Medicine and Biology, ACEMB, at Atlanta, Georgia, should have given the date of the conference as October 21-25, 1978. Readers desiring further information should contact Patricia I. Horner, Suite 404, 4405 East-West Highway, Bethesda, Md. 20014, 301-657-4142.



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